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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC, SANOFI-AVENTIS DEUTSCHLAND GMBH, and SANOFI WINTHROP INDUSTRIE, Plaintiffs, v. MYLAN GMBH, BIOCON LTD., BIOCON RESEARCH LTD., BIOCON SDN, BHD., and BIOCON S.A., Defendants.	C.A. No. 17-cv-09105-SRC-CLW

DEFENDANTS' PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

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I. INTRODUCTION

Sanofi asserted claims 21, 22, 25, and 30 of the U.S. Patent No. 9,526,844 ("the '844 patent"). As described more fully below, Sanofi failed to meet its burden of proving infringement of any claim by a preponderance of the evidence. Defendants, moreover, proved that the '844 patent is invalid as obvious over prior art and invalid for failing to satisfy the requirements of 35 U.S.C. § 112 with respect to written description and enablement. As a result, Defendants are entitled to judgment of non-infringement and invalidity.

II. PROPOSED FINDINGS OF FACT

A. The Proposed Pen Does Not Infringe The '844 Patent

1. Sanofi did not, and could not, meet its burden of demonstrating infringement of the asserted claims of the '844 patent by the Proposed Pen identified in Mylan GmbH's NDA No. 210605 (the "Proposed Pen") due to the stark structural and operational differences between the Proposed Pen and the pen claimed in the '844 patent. Trial Transcript ("TT") at 228:5-7, 229:11-17 (regarding structural differences).

2. The Proposed Pen was designed by Michael Quinn while he was employed by Becton Dickinson. DTX-2664 at 1. The trade name for the Proposed Pen invented by Mr. Quinn is "Vystra." TT at 222:22-223:4.

3. In the crowded field of the injector pen market—both now and at the time of the alleged invention in 2003—the common purpose and design constraints inherent in pen injectors has caused certain components such as housings, cartridge holders, dial sleeves, plunger rods, and so on, to be routinely used. TT at 226:15-227:2. As a result, designing a pen that avoids existing intellectual property can be difficult. Nevertheless, BD was able to develop and patent a

new, unique pen design that, as Mr. Quinn explained, achieved internal freedom-to-operate clearance. TT at 225:7-10, 228:1-2; DTX-2664; DTX-2291; PTX-1733.

4. In general, the components of the Proposed Pen are described in Mylan GmbH's NDA and documents prepared by BD. *See, e.g.*, PTX-350, PTX-351.

5. As Mr. Quinn explained, where the '844 patent describes a pen that operates in one way, the Proposed pen operates in the opposite. *See, e.g.*, TT at 228:5-7, 229:11-17. The clutch of the pen described in the '844 patent is engaged and rotates with the dose dial sleeve ("DDS") during dose setting. *E.g.*, TT at 228:19-22, 232:2-15; *see also* TT at 133:14-21, 133:25-134:2. The setback of the Proposed Pen is not engaged during dose setting and, unlike the dose set knob ("DSK"), the setback does not rotate. *E.g.*, TT at 228:23-229:1, 231:6-19; *see also* TT at 134:6-9; PTX-350 at MYL_IG00427442. The clutch of the pen described in the '844 patent is not engaged during dose administration and, unlike the DDS, the clutch does not rotate. *E.g.*, TT at 229:2-6, 230:5-10, 232:16-22; *see also* TT at 133:22-24, 134:3-5. The setback of the Proposed Pen is engaged and rotates with the DSK during dose administration. *E.g.*, TT at 229:7-10, 230:18-24, 231:20-24; *see also* TT at 134:6-12; PTX-350 at MYL_IG0042744-45. The clutch of the pen described in the '844 patent (and of SoloSTAR) is engaged and rotates with the DDS during dose correction. *E.g.*, TT at 229:24-230:7; *see also* TT at 133:14-21, 133:25-134:2. The setback of the Proposed Pen is not engaged during dose correction and, unlike the DSK, the setback does not rotate. *E.g.*, TT at 230:11-17; *see also* TT at 134:6-9; PTX-350 at MYL_IG00427446-47.

6. The differences between the pen described in the '844 patent and the Proposed Pen are significant. If the drive sleeve and DDS of the pen described in the '844 patent were connected during dose administration like the setback and DSK of the Proposed Pen, the pen

described in the '844 patent would not work. TT at 237:19-25. Likewise, if the setback and DSK in the Proposed Pen were not connected during dose administration, similar to the description in the '844 patent of the clutch 60 and dose dial sleeve 70 being disconnected during dose administration (TT at 133:14-21), the Proposed Pen would not function properly. TT at 238:1-6.

1. Claim 21: The Sleeve Is Not "Releasably Connected" To The Dose Indicator

7. Claim 21 requires "a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator." JTX-3 at claim 21. Sanofi accuses the setback in the Proposed Pen of being the claimed "sleeve" and the DSK of being the dose indicator, but the setback is not "releasably connected" to the DSK as required by claim 21.

8. Claim 21 expressly requires that the accused dose indicator and sleeve be "connected." JTX-3 at 8:16-49 (claim 21). Consistent with the claim, the specification of the '844 patent—which contains only one embodiment (*see* TT at 131:12-14, 577:3-16; *see generally* JTX-3)—describes how the clutch 60 and dose dial sleeve 70 are releasably ***connected*** during dose dialing but released during dose administration. JTX-3 at 5:60-63; *compare* TT at 228:19-22, 232:2-15 *with* TT at 229:2-6, 230:5-10, 232:16-22. The lone embodiment of the '844 patent involves inherent internal forces connecting the components when at rest and requires application of an external force to overcome the inherent connecting force and release the components from one another during operation, thus making them "releasably connected." *See, e.g.*, JTX-3 at 6:46-54 (describing use of force inherent in the design "to restore the connection between clutch 60 and the dose dial sleeve 70 when pressure is removed from the button 82"); TT at 236:3-9.

9. These components are "connected" at rest because the flexible arm 52 on the clicker 50 exerts a force that causes the clutch 60 and dose dial sleeve 70 to reconnect when pressure from the user is removed from the button. JTX-3 at 6:46-54; TT at 235:19-236:2. Because of this force, clutch 60 and dose dial sleeve 70 are always engaged (1) during dose dialing (*see, e.g.*, JTX-3 at 5:60-63), (2) during dose correction (*see, e.g.*, *id.* at 6:27-37), and (3) when the pen is not in use (*see, e.g.*, *id.* at 6:50-54). TT at 235:19-236:9. This is also true for operation of the embodying pen, the SoloSTAR. TT at 236:14-237:5. The specification of the '844 patent supports Mr. Quinn's opinion that the Person of Ordinary Skill in the Art ("POSA") would understand "releasably connected" to mean "connected" at rest or in a normal state with the ability to become "released" from that state. TT at 236:6-237:11; *see also* JTX-3 at 6:46-54.

10. Further, the POSA would have understood that different language, such as "connectable," would have been used to describe a design in which the components were not connected at rest. TT at 237:12-18. As a result, the POSA would understand "releasably connected" to mean that the sleeve and dose indicator are joined or "connected" to one another in their normal state and can be separated or "released" from that connected state only when acted upon by an outside force. TT at 235:19-236:2; *see also* JTX-3 at 6:38-50.

11. By contrast, the setback of the Proposed Pen is ***disconnected*** from the DSK when the Pen is at rest, during dose dialing, and during dose correction; the setback is only coupled to the DSK temporarily, during dose administration. PTX-350 at MYL_IG00427444. Dr. Reinholtz does not dispute that the Proposed Pen operates in this manner. TT at 101:8-11.

12. While the pen in the '844 patent has structures akin to a spring that ensure the clutch and dose dial sleeve are connected at rest (*i.e.*, flexible arm 52 on clicker 50), the Proposed Pen lacks any corresponding feature, further illustrating the difference between the pen

of the '844 patent and the Proposed Pen. TT at 236:6-237:11. There is no spring used or required to disengage the setback and DSK of the Proposed Pen, and no force is used or required to keep the setback and DSK in a disconnected state. TT at 228:23-229:1, 231:6-19; *see also* TT at 134:6-9; PTX-350 at MYL_IG00427442; *compare* PTX-350 at MYL_IG00427442-445 *with* JTX-3 at 6:38-54 (noting that "the connection between the clutch 60 and the dose dial sleeve 70" is restored "when pressure is removed from the button 82.").

13. The POSA would understand the Proposed Pen's configuration as "connectable," not "releasably connected." *See* TT at 235:19-236:2, 237:9-18. The '844 patent describes pen components that are forced together at rest and forced apart during dose administration. TT at 236:14-237:5. The components of the Proposed Pen, on the other hand, are neither forced together nor forced apart at rest. TT at 228:23-229:1, 231:6-19; *see also* TT at 134:6-9; PTX-350 at MYL_IG00427442. As a result, the Proposed Pen does not infringe claim 21. TT at 238:7-11.

14. Dr. Reinholtz argued that "releasably connected" encompasses components that can "be connected or disconnected" regardless of which phase of pen operation is connected and which is not. TT at 134:13-20. This viewpoint includes any disconnected parts, so long as they are capable of connection. TT at 134:13-20. Thus, Dr. Reinholtz ignores the limited description in the specification, which discloses only one embodiment. *See* TT 131:12-20. The position taken by Dr. Reinholtz is contrary to the plain and ordinary meaning of "connected." *See* TT at 235:19-236:2; *see also* JTX-3 at 6:38-50.

15. Moreover, under the proper interpretation described by Mr. Quinn in which the sleeve and dose indicator are connected in their nominal, resting state, Dr. Reinholtz admits that there is no infringement as to any of the asserted claims. TT at 135:21-136:19.

2. Claim 21: The Accused "Piston Rod Holder" Is Not Configured To Prevent The Piston Rod From Rotating During Dose Setting

16. Next, claim 21 requires a "piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating ***during dose setting***." JTX-3 at 8:27-29 (emphasis added).

17. Sanofi's expert, Dr. Reinholtz, was inconsistent with his identification of the claimed "piston rod holder" in the Proposed Pen. While Dr. Reinholtz initially said the tower core alone was the claimed piston rod holder (TT at 106:23-107:1), he changed his theory on cross examination to accuse the tower core in combination with the brake tower to satisfy this limitation. TT at 147:7-17, 148:19-23. Dr. Reinholtz made this change upon being asked whether, without a brake tower, the tower core could satisfy the portion of the claim limitation requiring that the piston rod holder be "rotatably fixed relative to the housing," admitting that the brake tower is "required as an intermediate component." TT at 147:23-148:3. Dr. Reinholtz agrees that the tower core alone cannot be the claimed piston rod holder because, "if you don't have the brake tower, the piston rod holder is not rotatably fixed to the housing." TT at 148:19-23.

18. Notably, Dr. Reinholtz conveniently interprets two components as satisfying one limitation when it suits him, such as here, and also interprets one component as satisfying two limitations elsewhere, such as regarding the "sleeve" in claim 21 and "clutch" in claim 25. TT at 147:7-15, 148:19-23, 149:17-150:20.

19. Neither the tower core alone nor the tower core combined with the brake tower satisfies claim 21, however, because they are not configured to prevent rotation during dose setting. TT at 239:6-240:7. As Mr. Quinn explained, the components of the Proposed Pen that allegedly "hold" the plunger rod are not configured to prevent the plunger rod from rotating

during dose setting because a different component, the setback, absorbs the torque that could otherwise reach the plunger rod when a user is setting a dose. TT at 239:6-15, 240:2-241:14; PTX-350 at MYL_IG00427442 ("Setback moves axially with the DSK, but without rotation due to a 1-way ratchet engagement with the brake tower"); *id.* at MYL_IG00427446 ("The ratcheting torque between the Setback and the Brake tower is significantly higher than the torque between the Setback and the Double clicker, hence dialing back the DSK does not cause the Setback to rotate in the injection direction[.]"); *see also id.* at MYL_IG00427447.

20. Unlike claim 21, the Proposed Pen uses the setback—the accused "sleeve" and "clutch"—to prevent rotation during dose setting, ***not*** a "piston rod holder." TT at 238:16-20. The POSA would understand the language of the "holder" limitation to refer to the manner in which the parts of the pen are put together and how they interact *during dose setting*, with a specific focus on how rotation is resisted during dose setting. TT at 240:23-241:10. The POSA would not understand the Proposed Pen to be configured in a manner such that the tower core and/or the brake tower "prevent the piston rod from rotating during dose setting" as required by claim 21. JTX-3 at 8:28-29; TT at 240:8-241:14. As a result, the Proposed Pen does not infringe claim 21. TT at 243:18-22.

21. With respect to the tower core of the Proposed Pen, the POSA would understand it to have two main functions: (1) to protect the lead screw and prevent it from buckling (TT at 240:10-16), and (2) to prevent the plunger rod from rotating *during dose injection* (dose administration) due to the rotation of the lead screw (TT at 240:17-22).

22. Dr. Reinholtz's experiment involving a modified tower core was flawed. Dr. Reinholtz testified that he used a knife to cut off the majority of the tower core and removed pieces of the Proposed Pen to test his theories. TT at 111:11-112:3, 139:19-24, 145:6-15. Doing

so, however, created a pen that differs from the Proposed Pen in several ways and therefore does not represent the Proposed Pen. Indeed, Dr. Reinholtz knew it would no longer work. TT at 143:2-10, 145:6-15.

23. First, for example, removal of the C-shaped, sleeve-like portion of the tower core eliminates the tower core's support of the lead screw and provides additional space in which the lead screw can move. TT at 241:23-242:11. Second, removing the dose stop component also creates space and allows the setback, and therefore the lead screw, to move more freely. TT at 112:4-7, 141:5-7, 242:6-8. Third, Dr. Reinholtz's conscious decision to advance the stopper away from the pressure foot further loosened the parts within the pen. TT at 141:23-142:18, 242:12-14, 242:23-25. Notably, the plunger rod in Dr. Reinholtz's modified pen would not rotate during dose setting if it was next to the rubber stopper—as it is during normal device operation and when not modified—such as when oriented with the needle pointing down. TT at 146:20-147:1, 242:12-14, 242:23-25. Dr. Reinholtz also used gravity to assist plunger rod movement. TT at 111:11-15.

24. Each of the modifications Dr. Reinholtz made to the BD Vystra serves to eliminate constraints on the plunger rod and subject it to additional vibration during dose dialing. TT at 242:15-243:11. Ultimately, the subject of Dr. Reinholtz's experiment is not the Proposed Pen at all—Dr. Reinholtz's modifications are "not recommended anywhere in the proposed labeling for Mylan's product," and he agrees that "[w]e don't want people to be doing this [modification]." TT at 143:8-12; *see also* TT at 140:24-141:3; *see generally* PTX-394.

25. There is no indication that Dr. Reinholtz's modified pen would be capable of extruding medicament, nor did Dr. Reinholtz expect that it could. TT at 145:6-15. From the moment he removed the long, slotted portion of the tower core, leaving behind only a fraction of

the structure, at the top of the tower core, (TT at 139:22-140:3; *see also* PTX-351 at MYL_IG00427452), the design of Dr. Reinholtz's experiment could not provide an accurate model for how the Proposed Pen functions or operates. TT at 243:12-17.

26. As a result, Dr. Reinholtz's "experiment" did not properly test the tower core's influence on the piston rod's possible rotation during dose setting because the unintended consequences of his modifications negate any probative value of the purported results. TT at 241:15-242:5. And Dr. Reinholtz's experiment does not show that claim 21 is met by the Proposed Pen. *See, e.g.*, TT at 242:15-243:11.

27. At most, Dr. Reinholtz demonstrated that some modified pieces of the Proposed Pen could be assembled in a way to allow the plunger rod to rotate when oriented needle-side-up and with the assistance of shaking and gravity. TT at 143:8-12, 146:20-147:1, 242:15-243:11. Claim 21, however, is not directed to preventing rotation when a pen is pointing upwards, vibrated or shaken, and where a person has placed an artificial gap between the rubber stopper and piston rod. JTX-3 at 8:16-49.

28. Dr. Reinholtz claimed that one of the pens in his experiment was an "unmodified Semglee pen just as it comes out of the box." TT at 112:25-113:11. Technically, he did not examine either pen just as it came out of the box because even the unmodified pen in the "experiment" had the plunger rod advanced two-thirds of the way into the cartridge. TT at 141:23-142:4, 241:20-243:11.

29. Moreover, the majority of Dr. Reinholtz's direct testimony regarding his experiment was given in response to speculative questions. *See, e.g.*, TT at 110:23-111:5 ("[I]f the keyed connection between the tower core and the plunger rod weren't present, ***could*** the plunger rod rotate during dose setting?") (emphasis added), 111:11-15 ("Have you done an

experiment to confirm that gravity or vibrations of the pen ***could*** cause the plunger rod to rotate during dose setting if th[e] keyed connection of the tower core weren't present?") (emphasis added). There is insufficient evidence to support a finding that the tower core, alone or in combination with the brake tower, satisfies the "piston rod holder" limitation of claim 21.

30. Further, as shown through Mr. Quinn's unrebutted testimony, the POSA would not use or consider an experiment like Dr. Reinholtz's in evaluating a pen injector or in determining how components of a pen injector function. TT at 243:12-17.

31. Aside from Dr. Reinholtz's experiment, the only documentary evidence Sanofi offered refers only to dose *administration*, not dose setting, and therefore is irrelevant to claim 21. *See* PTX-394 at MYL_IG00813814; *see also* TT at 110:2-12, 138:21-23, 239:6-240:7, 241:11-14. It is not necessary for a component downstream of the setback to "hold" the plunger rod during dose setting, because the setback absorbs any torque generated from the user dialing a dose. TT at 239:6-15, 240:2-241:10; PTX-350 at MYL_IG00427442, -446.

32. Accordingly, the Proposed Pen does not meet the limitations of claim 21 of the '844 patent. TT at 243:18-22.

33. Because claim 21 is not infringed, remaining asserted claims 22, 25, and 30, which depend from claim 21, are not infringed either.[1] TT at 136:6-19.

3. Claim 22: Claim 22 Is Not Infringed Because Claim 21 Is Not Infringed

34. Claim 22 requires "The drug delivery device of claim 21 where the piston rod has a circular cross-section." JTX-3 at 8:50-51.

35. Because claim 21 is not infringed, dependent claim 22 is not infringed either.

[1] Claim 25 further depends from claims 23 and 24, both of which are likewise not infringed.

4. Claim 25: Sanofi Failed To Identify The Required "Further" Clutch

36. Claim 25 depends from claim 24, which in turn depends from claim 23, which depends from claim 21. JTX-3 at claims 21, 23, 24, 25. Neither claim 23 nor claim 25 is infringed because claim 21 is not infringed. Further, as described below, the Proposed Pen does not satisfy the additional limitations of claims 23 and 25, and Sanofi has not carried its burden of proof on the issue of infringement with respect to claim 25.

a. Sanofi Failed To Identify A Separate Component As The "Clutch" Required By Claim 23 (And 24-25)

37. First, Sanofi failed to identify a separate component as the claimed "clutch" in claim 23 (and therefore also required by asserted claim 25). Claim 21 requires a "sleeve" that is releasably connected to the dose indicator and claim 23 requires the device of claim 21, "further comprising a clutch." JTX-3 at claims 21, 23. Sanofi, through Dr. Reinholtz, asserted that the setback satisfies the "sleeve" limitation of claim 21 and also the "further comprising a clutch" limitation of claim 23. TT at 121:6-8.

38. Dr. Reinholtz's approach ignores the plain language of the claim: claim 23 claims the device of claim 21, "***further*** comprising a clutch." JTX-3 at 8:52-53 (emphasis added). The inventors chose the word "further." Claim 23 thus requires a clutch beyond, or in addition to, what is already required by claim 21. *See* TT at 244:10-245:2.

39. Moreover, Sanofi does not provide any evidence to support Dr. Reinholtz's conclusory assertion that one component can satisfy both the "sleeve" limitation of claim 21 and also the "clutch" limitation of claim 23. *See* TT at 121:19-21. Nor has Dr. Reinholtz provided any detail as to his analysis beyond a statement that counsel informed him that he "didn't need to assume that [the claim limitations] were different components." TT at 150:10-20.

40. Notably, claim 30 also requires an additional component and uses similar "further comprises" language, and Dr. Reinholtz identifies a new component for claim 30 that is not already accused for claim 21. TT at 151:5-20. Dr. Reinholtz's position regarding claim 30 undermines his accusation of the setback as both the claimed "sleeve" in claim 21 and the claimed "clutch" in claims 23-25.

41. The claim language demonstrates that the applicants knew how to differentiate between the identification of a new element and merely specifying further limitations of a previously-recited element. *Compare* JTX-3 at 8:32-49 (reciting further limitations on existing elements by using "wherein" language) *with* JTX-3 at 8:52-53 (reciting a new element by using "further comprising" language). Moreover, if the "clutch" limitation of claim 23 were intended to refer back to the "sleeve" recited in claim 21, the applicants would not have used an indefinite article to introduce the claim limitation. *Compare* JTX-3 at 8:52-53 ("further comprising ***a*** clutch") *with* JTX-3 at 8:32-49 (using definite articles to reference previously-recited elements: "wherein: ***the*** housing . . . ***the*** dose indicator . . . ***the*** driving member . . . ***the*** sleeve . . . and ***the*** piston rod . . . .") (emphasis added)

42. Notably, Dr. Reinholtz agrees that if "further comprising" requires a separate component, there is no infringement. TT at 151:21-152:7. Accordingly, claims 23 and 25 are not infringed.

b. The Accused Clutch Teeth Do Not Click, As Required By Claim 25

43. Further, claim 25 is not infringed even if one component can satisfy the "sleeve" and "clutch" limitations. Claim 25 requires that "the clutch provides audible clicks," (JTX-3 at 8:57-58), and Sanofi identifies the "setback teeth" that click during dose correction as satisfying this limitation. TT at 122:24-123:9 (discussing claim 24, which claim 25 depends from).

However, these are ratchet teeth that have nothing to do with clutching. TT at 245:8-246:9, 263:15-264:1; *see also* TT at 598:8-9. Accordingly, the accused "clutch" does not provide audible clicks, and the Proposed Pen does not meet the limitations of claims 23 or 25 of the '844 patent. TT at 246:10-13.

5. Claim 30: The Accused "Dose Stop" Is Not A "Nut"

44. Claim 30 requires a "nut that tracks each set dose of medicament delivered." JTX-3 at 9:9-10. For this element, Sanofi identifies a component of the Proposed Pen called the "dose stop," which has only external threads. TT at 125:16-20; *see also* PTX-350 at MYL_IG00427448-49; PTX-351 at MYL_IG00427452; TT at 247:13-20. This design does not satisfy the requirement of claim 30 that the component be a "nut" that tracks set doses of medicament. TT at 247:13-20.

45. Sanofi asserts through Dr. Reinholtz that "some nuts have external threads," and that the claim does not require internal threads, (TT at 126:3-4, 126:8-10), but Dr. Reinholtz never asserted that such a component without internal threads would classify as a nut ***to the POSA***. *See generally* TT at 125:13-129:15. To the contrary, when asked on direct what he meant when he said that "some nuts have external threads," Dr. Reinholtz merely stated that "[t]here are components called flare nuts. Some kinds of lug nuts in automobiles have only external threads." TT at 126:5-7.

46. Even if the "nut" recited in claim 30 could lack internal threads and have only external threads, there is no evidence that the Proposed Pen belongs to the category of externally-threaded nuts. *See generally* TT 125:9-129:15. Dr. Reinholtz does not opine, nor does Sanofi provide evidence to support the argument, that the dose stop of would be in that category. *Id.*

47. Notably, Dr. Reinholtz admits that not all externally-threaded components are "nuts." TT at 153:22-25 (admitting that "[e]xternally threaded components certainly can be

screws."). In fact, when confronted with a picture of a component bearing only external threads (characterized by Dr. Reinholtz as a "pipe nipple"), Dr. Reinholtz admitted that he "generally wouldn't describe that as a nut." TT at 154:9-19.

48. To the contrary, Dr. Reinholtz admitted that nuts are customarily internally-threaded. TT at 152:10-13. Further, according to Sanofi's own expert Dr. Slocum, removing internal threads from a "nut element" would have a result such that "in some respects, it's no longer a nut." TT at 454:20-24. As a result, the POSA would understand the plain and ***ordinary*** meaning of "nut" to be a component with internal threads.

49. The '844 patent's specification is consistent with the POSA's understanding that nuts have internal threads. TT at 246:21-247:12; JTX-3 at 4:26-35. Items with only external threads, like the accused dose stop, or pipe nipples, are not typically referred to as nuts. TT at 247:23-248:7; *see also* TT at 264:11-21; DTX-2291 at ¶ 141 (describing a "half-nut ***like*** element," thereby illustrating that the element is not actually a half-nut) (emphasis added). Indeed, both parties' experts agree that the usual meaning of "nut" refers to an internally-threaded component (TT at 152:10-13; 247:8-12), demonstrating that the plain and ordinary meaning of nut does not include components that lack internal threads.

50. Accordingly, the Proposed Pen does not meet the limitations of claim 30 of the '844 patent. TT at 248:8-11.

51. For the foregoing reasons, the Proposed Pen does not infringe claims 21, 22, 25, or 30 of the '844 patent. TT 248:12-16.

B. The '844 Patent Is Invalid

1. The Prior Art Renders The '844 Patent Obvious

52. Defendants have more than met their burden of proving that the '844 patent is obvious to a POSA in view of the prior art.

53. Sanofi stipulated that almost all limitations are met by the prior art, and as explained below the evidence at trial including admissions by Sanofi's expert, Dr. Slocum—show that the remaining limitations were also included in the prior art asserted by Defendants.

54. Obviousness is determined from the perspective of a hypothetical POSA as of the priority date, which is no earlier than March 3, 2003 for the '844 patent. *See* JTX-3 at (30). In this case involving the '844 patent, the "art" or field of the invention is that of injector pens. JTX-3 at 1:25 ("The present invention relates to pen-type injectors . . . ."). The '844 patent discloses only an injector pen, it does not describe or claim any other types of devices that can be used to inject medication. *See generally* JTX-3.

a. The POSA

55. Mr. Leinsing explained that the POSA is a person that by "educational [or] practical experience, [had] at least the equivalent of a bachelor's degree in mechanical engineering or related field. That person would also have approximately three years of practical experience with medical device design and manufacturing, or at least the understanding of the basic medical design and manufacturing as it pertains to pen injectors, gears, pistons, and those types of components." TT at 278:14-23.

56. He further explained that his opinions would be the same even if they were premised upon Dr. Slocum's definition of the POSA. TT at 279:7-10.

57. Notably, Mr. Leinsing was proffered and accepted as an expert in the area of pen injectors and had experience with pen injectors before the priority date. TT at 277:10-17. Mr. Leinsing also worked for Ivac, a subsidiary of Eli Lilly, in the mid 1990s and performed work on development of a dual-acting pen injector for Eli Lilly. *Id.* at 276:2-15; DTX-2262 at 2-3. Mr. Leinsing also has 34 patents on medical devices. *Id.* at 276:16-17; DTX-2262 at 3-4.

58. Dr. Slocum, by contrast, had no experience with pen injectors until this case and was only offered as an expert in mechanical systems, not pen injectors. TT at 519:20-23, 521:8-10; TT at 444:18-20; *see also* PTX-1647. As a result, while Dr. Slocum may meet the definition of the POSA by having mechanical engineering education and experience with other types of medical devices, he had no professional knowledge of injector pens until he began working for Sanofi in this litigation. *See id.*

59. The situation is similar for the parties' infringement expert witnesses. Mr. Quinn designed the BD Vystra device, the Proposed Pen, and in connection to that studied pen injectors in the field. TT at 222:19-21, 227:22-228:4; *see also* DTX-2664. Dr. Reinholtz has never designed an injector pen, has not published papers about injector pens, none of his grant proposals showed injector pens, and before this case he had never held an injector pen in his hands in a professional capacity. TT at 130:11-131:1; *see also* PTX-1646.

b. Steenfeldt-Jensen In View Of Chanoch Render The Asserted Claims Obvious

60. Sanofi agreed that Steenfeldt-Jensen describes a pen injector that meets each of the limitations recited in claim 21, except "a driving member having a third thread" that engages with the external thread of a piston rod. ECF No. 529 at 4-6; TT at 295:4-296:20. Sanofi is incorrect, however, as Steenfeldt-Jensen teaches alternative embodiments having a threaded driving member that satisfy the remaining limitations not addressed by the parties' stipulation. *See* § II.B.1.b.i., below. Dr. Slocum even admitted on cross-examination that the driving member limitation is met by at least Steenfeldt-Jensen, claim 6. TT at 533:11-542:21; *see also* DTX-2282 at claim 6.

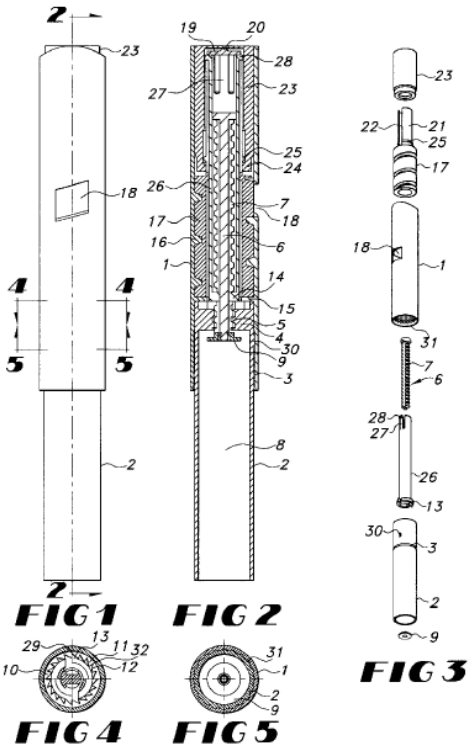
61. To the extent there was any doubt, Sanofi also stipulated that Chanoch discloses a threaded driving member, as required by claim 21 of the '844 patent. ECF No. 529 at 5.

i. Claim 21: Steenfeldt-Jensen And Chanoch Teach An Internally Threaded Driver Tube

a) Steenfeldt-Jensen

62. Sanofi has stipulated that Steenfeldt-Jensen, issued in 2001, is prior art. ECF No. 529 at 2 ("Defendants have identified certain prior art to the '844 Patent, including U.S. Patent No. 6,235,004 ('Steenfeldt-Jensen')."").

63. Steenfeldt-Jensen describes five primary embodiments of injector pens with components that drive a piston rod to dispense medicine. *See generally* DTX-2282; *see also id.* at 4:62-5:28 (describing figures for five embodiments), 2:39-3:5. The first embodiment is shown in Figures 1-5 (reproduced below).



64. When the user presses the button in the first embodiment, dose scale drum 17 rotates piston rod guide 14 (which has a slotted bore and is described as "integral" with a driver tube 26), which causes the piston rod 6 to rotate as well. DTX-2282 at 6:35-41, 7:17-35, Figs. 1-

5. When rotated by the driver tube 26 (via the piston rod guide 14), the piston rod 6 screws and advances through end wall 4, which includes a central bore with an internal thread 5 that mates with an external thread 7 of the piston rod 6. *Id.* at 5:55-58, 7:31-35. Steenfeldt-Jensen states that the structure contained within end wall 4—a threaded bore—forms "a nut member." *Id.* at 7:41-43.

65. The fifth embodiment is shown in Figures 15-17 (reproduced below). As shown in the Figures, the drive mechanism of the fifth embodiment includes driver tube 85, piston rod 6, and member 40. *See* DTX-2282 at 11:11-19, FIGS. 15-17; *see also id.* at 7:49-51 ("Elements corresponding to elements in the embodiment described with references to the FIGS. 1-5 are provided with the same reference numbers."), 5:57 (numbering the piston rod as component 6), 8:35-42-(providing threaded member as a separate component 40 having end wall 4). The driver tube has a slot with rounded ends that engages with the piston rod so that they rotate together, but the piston rod may move axially relative to the driver. *Id.* at 11:15-19. Piston rod 6 is also threadedly engaged with member 40, which is axially and rotationally fixed relative to the housing. *Id.* at 8:35-42, 11:6-19. When the user pushes on the button, driver tube 85 rotates piston rod 6 due to the flats on piston rod 6 engaged with the slot in driver tube 85, which advances piston rod 6 through member 40 to dispense medicine. *See id* at

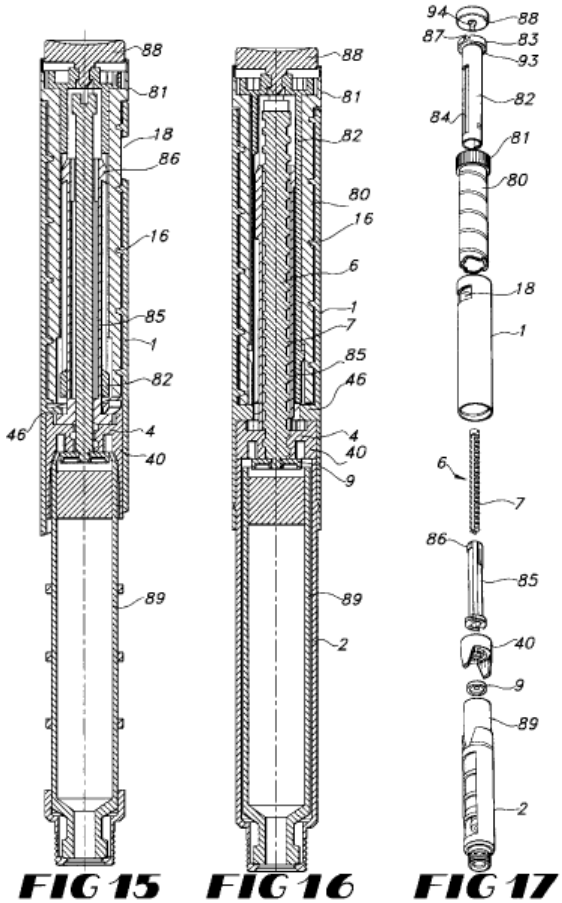


FIG 15 FIG 16 FIG 17

12:10-13; *see also* TT at 297:5-300:14 (Mr. Leinsing describing operation of Steenfeldt-Jensen). As is clear, the drive mechanism during dose administration in first and fifth embodiments are nearly identical, as Dr. Slocum admits. TT at 530:17-23, 531:12-25.

b) Steenfeldt-Jensen Teaches A Threaded Driving Member

66. Dr. Slocum's own textbook describes that leadscrews can operate by holding the nut and turning the screw or holding the screw and turning the nut. TT at 497:5-498:1 PTX-657 at SANOFI5_00018783 ("The principle of a leadscrew and nut has been used for centuries . . . . By turning a leadscrew and holding a nut so that it does not rotate, the nut moves along the length of the leadscrew. Alternatively, the shaft can be held and the nut turned."). The fifth embodiment situates the slot (*i.e.*, the "piston rod guide") within the driver tube 85 and the internally-threaded bore (*i.e.*, the "nut member") within the member 40, but Steenfeldt-Jensen expressly teaches an alternative option that exchanges the slot and threaded bore in the driver tube 85 and member 40, such that the driver tube alternatively comprises internal threads. DTX-2282 at 3:15-17, 3:41-47; TT at 301:6-13.

67. Further, after description of its first embodiment, Steenfeldt-Jensen states that "[e]mbodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube and such embodiment will not be beyond the scope of the invention." DTX-2282 at 7:41-47.

68. As Mr. Leinsing explained, a POSA would have understood Steenfeldt-Jensen as teaching two alternative approaches for the driver tube: (1) as in the illustrated embodiment, the driver tube may include the rectangular bore such that the piston rod is rotated relative to the nut member; or (2) as in the alternative, the driver tube may include the internally-threaded bore such that the nut member is rotated relative to the piston rod. TT at 299:23-303:13.

69. Indeed, Steenfeldt-Jensen acknowledges the two approaches and their widespread use in the industry at the time. *See* DTX-2282 at 1:30-40, 2:7-22.

70. As background, Steenfeldt-Jensen explains that "[m]ost dose setting devices work with a threaded piston rod co-operating with a nut where the nut and the piston rod may be rotated relative to each other." *Id.* at 1:31-33.

71. In some cases, "one of the elements, the nut or the piston rod, is kept inrotatable and the other is allowed to rotate a set angle depending on the set dose, whereby the piston rod is screwed a distance through the nut." *Id.* at 1:36-40.

72. Steenfeldt-Jensen goes on to discuss a specific prior-art injection pen as an example where, when the button is screwed back into the housing during dose dispensing, rotation is transmitted to the driver "which has a nut co-operating with a threaded piston rod which is made inrotatable in a housing." *Id.* at 2:7-22.

73. Dr. Slocum, moreover, admitted that a POSA, upon reading Steenfeldt-Jensen, would exchange the threads and slot:

> Q. … "Embodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube, and such embodiment will not be beyond the scope of the invention." You see that; right?
> A. That's what the words say.
> Q. That's what the words say. And you don't disagree that implementing what that word says involves flipping the slot and the thread; correct?
> A. ***If you just read the words, you will flip them***.

TT at 530:1-11 (emphasis added); *see also* TT at 306:6-307:13 (describing predictable operation of each configuration as demonstrated by Sanofi-created animation).

74. Dr. Slocum also admitted on cross examination that claim 6 in Steenfeldt-Jensen expressly claims a threaded driver. TT at 533:11-542:21; *see also* DTX-2282 at claim 6.

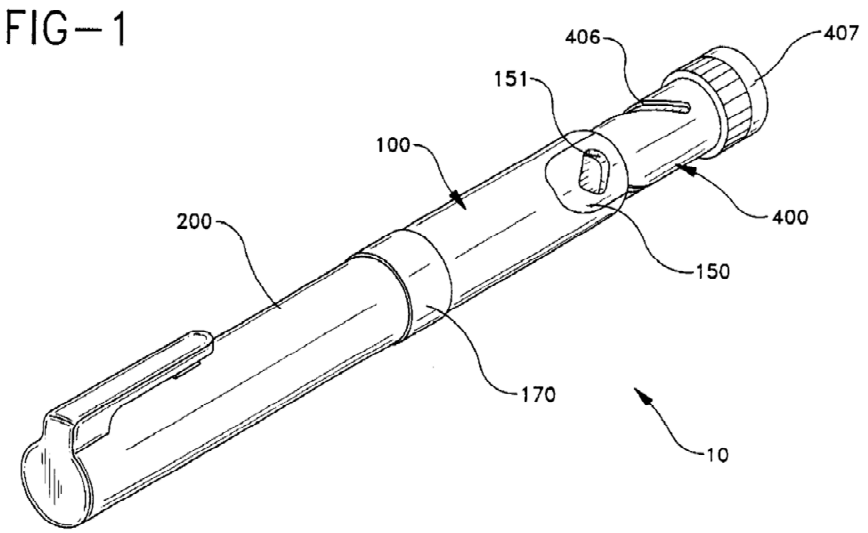
75. As a result, it cannot be disputed that Steenfeldt-Jensen satisfies claim 21.

c) Chanoch Teaches A Threaded Driving Member

76. Sanofi's arguments that using a threaded driver would be "stupid" or that a POSA would not do so (*see* TT at 525:14-528:18)—despite Steenfeldt-Jensen's express teachings and claims—are directly rebutted by Chanoch. Dr. Slocum's 2019 opinions at trial, with no prior experience with injector pens, cannot trump what was actually taught in the prior art before the priority date. TT at 521:8-523:17; Section II.B.1.a, *supra*.

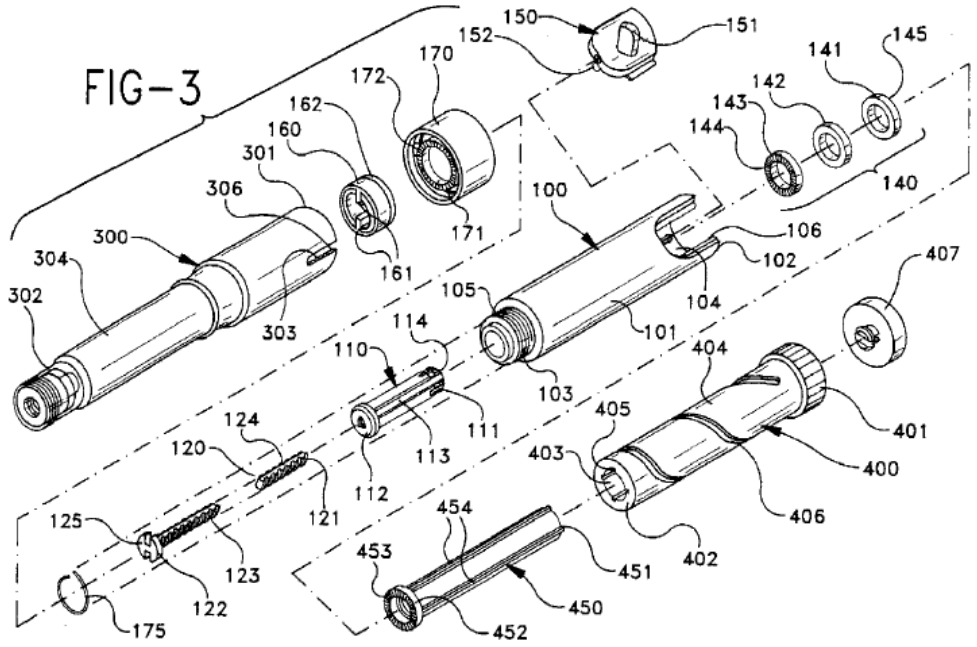
77. Chanoch is a U.S. Patent directed to a "medication delivery pen" that issued in 1997. DTX-2280.

78. Sanofi stipulated that Chanoch is prior art. ECF No. 529 at 2 ("Defendants have identified certain prior art to the '844 patent, including … U.S. Patent No. 5,674,204 ('Chanoch')."). In general, Chanoch describes an injector pen shown in Figure 1 that allows a user to dial, select, and dispense a dose of medication. DTX-2280 at Abstract, Fig. 1.

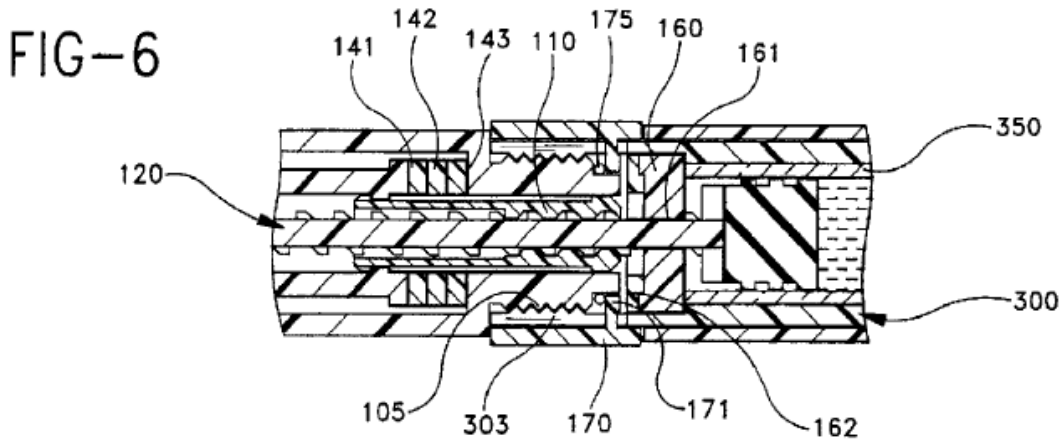


Chanoch describes a threaded driving member engaged with a threaded piston rod, as Sanofi agreed by stipulation. ECF No. 529 at 5.

79. Like driver tube 85 in Steenfeldt-Jensen, Chanoch describes a nut 110 that is radially enlarged at a distal end so that the nut 110 is axially fixed but free to rotate relative to the housing. DTX-2280 at 4:50-55, FIG. 3.



80. Along its internal surface, the nut 110 includes threads that engage external threads 123 of a leadscrew 120, which is rotatably held relative to the housing during dose dispensing. *Id.* at 5:44-52, 8:5-31, FIG. 6.



81. When the user pushes on the button during dose dispensing, nut 110 is rotated, thus driving the leadscrew 120 axially to dispense medication. *See id*. at 8:5-32.

82. To the extent the POSA had any questions regarding whether the alternatives described in Steenfeldt-Jensen could be implemented, those questions would be resolved by Chanoch, admitted prior art in the same injector pen field as Steenfeldt-Jensen and the '844 patent. TT at 310:10-311:22.

d) Dr. Slocum's Arguments Are Unavailing

83. Despite the fact that the prior art plainly included threaded driving members, Sanofi relies entirely on Dr. Slocum to argue that a POSA would not be motivated to "modify" Steenfeldt-Jensen because of concerns about injection force. Dr. Slocum's opinions are flawed for several reasons.

i) Dr. Slocum Improperly Disregards Steenfeldt-Jensen's Teachings, But The POSA Would Not

84. First, Dr. Slocum's reading of Steenfeldt-Jensen improperly treats the prior art patent as if it is a collection of independent references, rather than understanding the teachings of the patent as parts of a related whole. For example, Dr. Slocum opined that Steenfeldt-Jensen does not teach a threaded driver, going so far as to characterize Steenfeldt-Jensen's express teaching of the swap as likely a "lawyer add-on" even though he had no support for that assertion. TT at 525:21:12. To support this claim, Dr. Slocum asserted that Steenfeldt-Jensen's suggestion for an internally threaded driver tube is limited only to the first embodiment. But in doing so, Dr. Slocum ignores teachings in the Steenfeldt-Jensen patent; the POSA, however, would consider all of the teachings in Steenfeldt-Jensen. TT at 301:14-305:2.

85. Sanofi attempted to bolster this argument by relying on Steenfeldt-Jensen's provisional application, which Dr. Slocum stated disclosed only the first and second

embodiments. *See* TT at 477:23-478:24; PTX-1722. But the embodiments in the provisional application are irrelevant to the question of what would be obvious to the POSA in view of the issued Steenfeldt-Jensen patent.

86. Dr. Slocum's opinion is also flawed because it improperly ignores the express teachings in the description of the invention and the undisputed substantial similarities between the first and fifth embodiments that would have led the POSA to understand the applicability of concepts across the disclosed embodiments. *See, e.g.*, DTX-2282 at 3:15-20 (stating, in the summary of its invention, that "movement of th[e] button is transformed into rotation of the piston rod (or the nut member) relative to the nut member (or the piston rod)), 3:41-47 (stating, in the summary of its invention, "the dose scale drum must be coupled to a diver rotating the piston rod (or the nut member) relative to the nut member (or the piston rod) when the injection button is pressed); TT at 303:14-304:23.

87. Indeed, Dr. Slocum admitted that the first and fifth embodiments operate the same way during dose dispensing. TT at 531:12-22. This is relevant because Steenfeldt-Jensen expressly teaches the implementation of either alternative in terms of dose dispensing. *See, e.g.*, DTX-2282 at 3:15-20 ("***When the injection button is pressed***, the movement of this button is transformed into a rotation . . . ." (emphasis added)), 3:41-47 ("In this case the dose scale drum must be coupled to a diver rotating the piston rod (or the nut member) relative to the nut member (or the piston rod) ***when the injection button is pressed***." (emphasis added)), claim 6 ("a piston rod drive ***for driving said piston rod in a distal direction inside the cartridge*** . . ., wherein rotation of said first part in a first direction relative to said second part ***drives the piston rod in a distal direction***" (emphasis added))

88. There is no need to "modify" Steenfeldt-Jensen to arrive at the threaded driving member required by '844 patent, claim 21 when Steenfeldt-Jensen expressly teaches one, as described above.

ii) Dr. Slocum Incorrectly Emphasizes Injection Force, Which Was Not The POSA's Focus In 2003

89. Second, Dr. Slocum's opinion incorrectly assumes that the POSA in 2003 would rely on injection force as the ultimate guiding principle when designing an injector pen even though the only support for Dr. Slocum's assumption is what he was told by Mr. Veasey during the pendency of this case. *See* TT at 521:8-523:11.

90. In reality, DCA documents at the time of the alleged invention show that when designing the SoloSTAR pen, Sanofi and DCA only gave injection force the weight of a "marketing / project desirable" characteristic, rated a "3" on a scale from 1 to 5 and behind numerous other considerations rated 4 ("marketing / project fundamental") and 5 ("Legal requirement (ISO Standard)"). PTX-214 at DCA0005485; *see also* TT at 75:18-77:4.

91. In addition, DCA documents at the time show that designs with a higher injection force relative to FlexPen were considered as closely meeting the design criteria, referred to as "Target Product Profile or TPP," set by the team. TT at 45:2-12, 71:24-73:12. For example, Concept 2, which theoretically had a six percent (6%) higher injection force than FlexPen, was noted as "probably closest to the TPP, both quantitatively and qualitatively." DTX-2276 at DCA0000039, DCA0000058; TT at 69:16-70:19, 72:3-12. Concept 9, which theoretically had a fifty-nine percent (59%) higher injection force than FlexPen, was similarly noted as being "[r]elatively close to the TPP." DTX-2276 at DCA0000043, DCA0000061; TT at 71:11-17, 72:19-73:12.

92. Moreover, Dr. Slocum admitted that he could not identify ***any*** prior art teaching the alleged paramount importance of lowered injection force. TT at 591:7-23.

93. In fact, the prior art does not highlight injection force as a sole motivating factor, and instead discusses numerous factors as important to injector pen design, including manufacturability, the ability to correct a dose, and a low number of components. *See, e.g.*, DTX-2282 at 1:16-29 (stating "[a] number of demands are set" for injector pens, such as "easy an[d] unambiguous" dose setting, ease in "cancel[ing] or chang[ing] a wrongly set dose," and, for disposable pens, "cheap and made of materials suited for recycling" with minimal number of parts and materials), 12:15-16; DTX-2283 at 1:5-7, 2:27-33 (providing "a medication delivery pen having a simple mechanism for setting the desired dose that uses as few parts as necessary without losing functionality or standard features"); TT at 305:9-13.

94. Additionally, even if a POSA were guided primarily by injection force, the spreadsheet that Dr. Slocum relies on to claim that using the threaded driver taught by Steenfeldt-Jensen would raise injection force suffers from several flaws.

95. For example, Dr. Slocum's spreadsheet only calculated forces that could increase the injection force and failed to account for the removal of forces that would result in a decrease. TT at 561:9-562:25, 559:24-560:17.

96. Because he had no professional experience with injector pens before this case, Dr. Slocum relied on Mr. Veasey's empirical claims that 0.1 as the coefficient of friction despite his own teaching at MIT that the coefficient of friction for commonly-used plastics in mechanical devices can range from 0.05 to 0.1. TT at 521:8-523:11, 558:8-559:8.

97. Dr. Slocum agreed in both instances that accounting for these differences would reduce the "51%" ratio, which undermines his claims that the POSA would not implement the

alternative embodiment described in Steenfeldt-Jensen. TT at 557:10-19, 559:24-560:17, 561:5-562:25.

98. The values used in Dr. Slocum's spreadsheet underscore Dr. Slocum's unyielding acceptance of Mr. Veasey's empirical claims and fail to account for the POSA's ordinary skill (and creativity), which would easily enable the POSA implementing Steenfeldt-Jensen's alternative to reduce the injection force, if that was even a concern necessary to address. As Mr. Leinsing explained, the POSA could reduce injection force by adding lubricants, or reducing the size of the sliding surface of the driver, which would reduce the amount of friction. TT at 307:21-310:5 (noting addition of lubricants and routine changes to the diameter of the rotating "thrust bearing" on the driver).

99. Moreover, even accepting Dr. Slocum's alleged 51% for the sake of argument, a POSA would have appreciated that this increase would still result in a device that achieved an injection force within an acceptable range and would therefore not have been discouraged from implementing the alternative described in Steenfeldt-Jensen where the driver tube has internal threads. Specifically, for Steenfeldt-Jensen's illustrated fifth embodiment, Dr. Slocum's spreadsheet shows a user injection force of 10 Newtons (N) to achieve a particular output force to dispense medicine. TT at 556:21-23. Dr. Slocum testified that "Mr. Veasey verified" that this input force was "a fine number to pick in terms of thumb injection." TT at 546:21-547:16; *see also* DTX-2925 (showing a screenshot of Dr. Slocum's spreadsheet). According to Dr. Slocum's modeling, in the alternative configuration, a user would need to input a force of 15.1 N to achieve the same dispensing output force. *See* TT at 555:13-19. This input force—15.1 N—would still be viewed as an acceptable injection force, and indeed, would have even met DCA's own design objectives, which required a design that achieved, at minimum, a mean peak

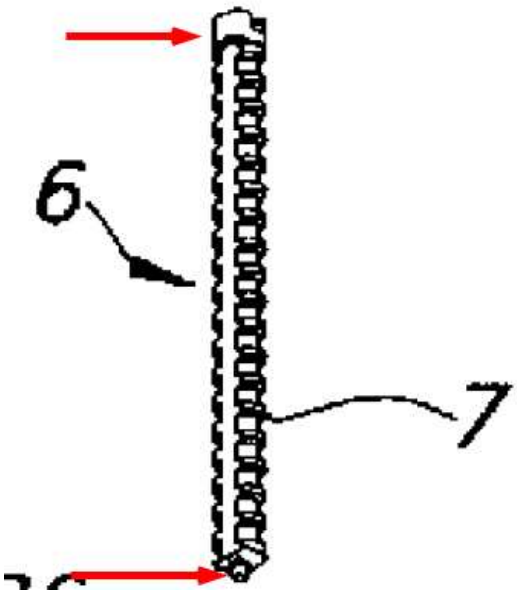
dispensing force of 15.4 N. *See* TT at 68:19-24; PTX-12 at SANOFI_00006422 (minimum requirement of 15.4 N).

ii. Claim 22: Steenfeldt-Jensen And Chanoch Render Obvious A Piston Rod That Has "A Circular Cross-Section"

a) Steenfeldt-Jensen Discloses A Piston Rod With A Circular Cross-Section

100. Steenfeldt-Jensen and Chanoch render claim 22 obvious because they disclose piston rods with circular cross-sections. TT at 316:5-10; DTX-2282 at FIGS. 8 (piston rod 6), 17 (piston rod 6); DTX-2280 at FIG. 3 (leadscrew 120).

101. Although Steenfeldt-Jensen describes the piston rod as "non-circular," that addresses only a portion of the piston rod, ignoring the ends, which Mr. Leinsing explained have a circular cross-section. TT at 314:21-315:9, 316:5-10; *see also* DTX-2882 at MYL_IG00427930, Fig. 17 (piston rod 6) (reproduced and annotated here).



102. Dr. Slocum's opinion that Steenfeldt-Jensen and Chanoch allegedly lack a piston rod with a circular cross-section appears to rest on the theory that the piston rod must be circular across the entire length of the piston rod. TT at 315:13-17, 490:20-491:18.

103. This improperly reads limitations into the claim, however, as claim 22 only requires "a" (one) circular cross-section. JTX-3 at claim 22.

104. There is no requirement in claim 22 for what fraction of the piston rod must be circular or where the circular cross-section must be (ends, middle, etc.). *Id.*

105. As Dr. Slocum admitted on cross examination, a piston rod can have more than one "cross section." TT at 570:13-571:1, 573:2-574:24, 576:13-16.

106. Dr. Slocum also admitted that piston rods may have "journals" on the end, which can be round and act as bearings. TT at 490:20-491:10; *see also id.* at 570:17-571:1 (Dr. Slocum describing a portion of the Giambattista piston rod as circular); DTX-2283 at Fig. 1 (showing piston rod 9 with an end labeled 92).

107. Dr. Slocum and Dr. Reinholtz's testimony are inconsistent with respect to distinguishing between features on a single component. Dr. Slocum tried to distinguish between cross-sections of the piston rod based on whether they were "journal" bearings or threaded, based on their function. TT at 491:2-491:13. Dr. Reinholtz, however, ignored the fact that the teeth accused of providing audible clicks during dose cancelling for claim 25—allegedly part of the claimed "clutch"—are uninvolved with the clutching function. TT at 122:4-12, 124:6-11; *cf.* TT at 263:15-264:1 (Mr. Quinn explaining that the accused teeth are not clutch teeth and only are involved in a clicking function). Whereas Dr. Reinholtz analyzes a component as a whole, Dr. Slocum's arguments for validity require parsing out portions of a component by function. Sanofi cannot have it both ways.

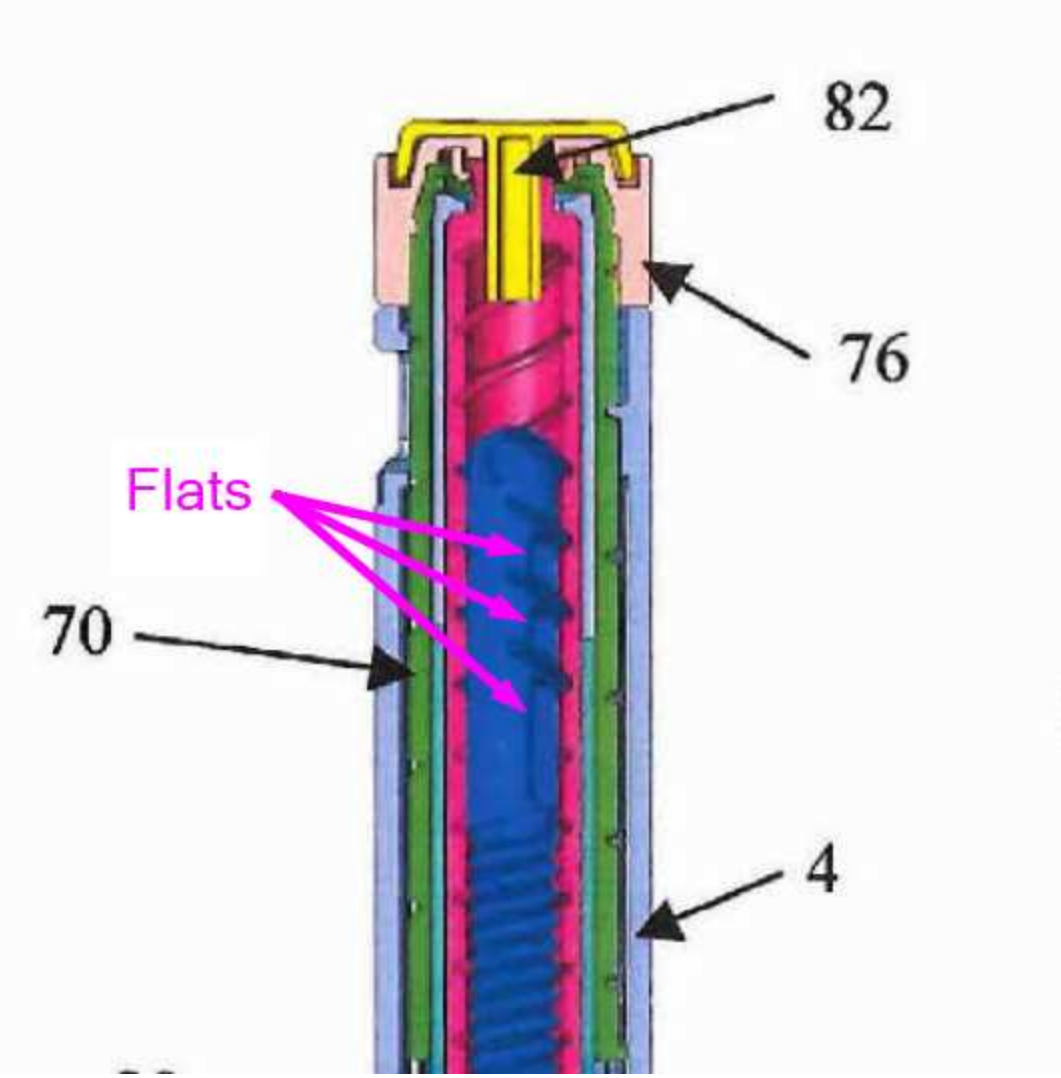
b) The Proper Interpretation Of "A Circular Cross-Section" Is Generally Circular

108. The POSA would interpret claim 22 in view of the '844 patent specification. The '844 patent describes the piston rod as of "***generally*** circular section," not "perfectly" circular cross-section, and depicts the piston rod as having multiple types of cross sections, including sections that are not circular (as described above). JTX-3 at 3:66; TT at 312:12-25, 314:7-20.

109. Consistent with description of the piston rod as having a "generally" circular cross-section," the '844 patent teaches that the piston rod has two sets of threads, each of which result in a non-circular cross-section. *See* JTX-3 at 3:65-4:7; TT at 312:12-25, 314:7-20.

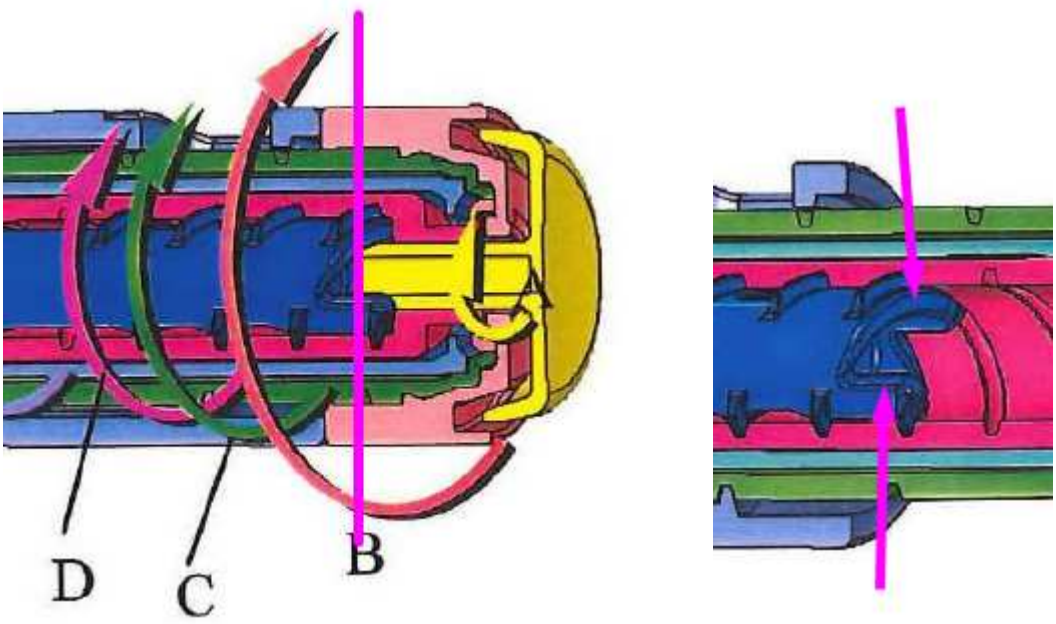
110. Moreover, one of the sets of threads is described as "part" threads, meaning they do not encircle the full 360 degree circumference of the piston rod, again resulting in a non-circular cross-section in the lone and preferred embodiment of the '844 patent. JTX-3 at 4:3-7, FIGS. 2, 9.

111. In addition to the specification and figures of the '844 patent as issued, the Great Britain application to which the '844 patent claims priority, which has clearer figures than the '844 patent, shows flat areas between the threads on the piston rod that result in a non-circular cross-section. *See* DTX-2850 at FIGS. 3, 9-11; TT at 313:1-314:6. For example, DTX-2850, Figure 3 shows flats:



Id. (purple annotations added).

112. Like Figure 9 in the '844 patent, DTX-2850, Figures 9-10 also show horn-like features on the button end of the piston rod that result in a non-circular cross-section:



DTX-2850 and Figs. 9-10 (purple annotations added).

113. In view of the '844 patent's description, and the GB priority application, the POSA would not interpret claim 22 as requiring a "perfectly" circular cross-section "along its length"; rather, the POSA would understand claim 22 as requiring "a" (at least one) cross-section that is "generally" circular. *See* TT at 315:19-23; JTX-3 at 3:65-4:7, FIGS. 2, 9; DTX-2850 at FIGS. 3, 9-11.

114. Mr. Veasey stated that the SoloSTAR pen—which he testified corresponded to both development Concept 12 described in the GB application and the '844 patent—has an "***essentially*** round" piston rod. TT at 52:19-21, 57:1-2, 57:10-12, 59:13-15, 80:22-25.

115. By contrast, Dr. Slocum's argument that claim 22 refers to the "root diameter" of the piston rod and only to the portion "that does the work of providing the axial force" finds no basis in the '844 patent. *See* TT at 491:24-492:15.

116. Steenfeldt-Jensen and Chanoch disclose piston rods with circular cross-sections and generally circular cross-sections. DTX-2282 at FIGS. 8 (piston rod 6), 17 (piston rod 6); DTX-2280 at FIG. 3 (proximal end 121 of piston rod 120); TT at 314:21-315:9, 316:5-10.

117. Sanofi's accusation that the plunger rod of the Proposed Pen has a circular cross-section is contradicted by Dr. Reinholtz's assertion that a so-called "key" on the plunger rod in the Proposed Pen prevents rotation of the plunger rod during all phases of operation. Dr. Slocum's testimony makes clear that a round cross-section would be a bearing (TT at 491:8-9), while a non-round shape (a "polygon") would transfer torque (*id.* at 491:9-10). The POSA would thus understand that a cross-section cut through the "key" on the accused plunger rod would result in a non-circular cross-section—like the non-circular cross-sections Dr. Slocum states are present in Steenfeldt-Jensen and Chanoch. *See id.* at 108:8-17 ("[T]here's a slot in the tower core that engages with a tab in the piston rod . . . it's like a keyed connection that only allows the piston rod to slide axially relative to the tower core. It does not allow [the plunger rod] to rotate relative to the tower core . . . ."); DTX-2282 at 2:47-49 (Steenfeldt-Jensen describing "a piston rod drive" having "a piston rod guide in relation to which the piston rod is axially displaceable but not rotatable"), 11:15-19; DTX-2280 at 5:55-62 (Chanoch describing "an anti-rotation ring 160 having a pair of tabs 161" that "slidabl[y] engages groove 124 on lead screw 120" such that "lead screw 120 can slidably move relative to anti-rotation tabs 161, but is prevented from rotating relative to tabs 161"), 8:22-26.

118. The POSA would understand that Steenfeldt-Jensen and Chanoch disclose and render obvious a piston rod that has a circular cross-section. TT at 316:5-10.

iii. Claim 30: A "Nut That Tracks Each Set Dose Of Medicament" Is Obvious Over Steenfeldt-Jensen And The Prior Art

119. It was common in the art as of 2003 to use a nut member over threads to track medication dosing, as Mr. Leinsing explained in his unrebutted testimony. TT at 317:19-22.

120. The ISO standards, which DCA documents describe as "legal" requirements and rate at the highest level of importance (PTX-214 at DCA0005485), would cause the POSA to add a nut because the standards require tracking doses so the pen "does not allow a larger dose to be preset than is left in the cartridge." *See* DTX-2267 at SANOFI_00375974; TT at 316:13-317:22.

121. Sanofi did not dispute that the POSA would be motivated to add and could and would add a dose tracking nut. *See generally* TT at 317:14-320:4, 444:23-492:16.

122. Moreover, FlexPen—which, as described below, was known and used by others prior to the '844 patent's filing date—and Klitgaard demonstrate that it was known in the prior art to use a nut that tracks each set dose of medicament. TT at 318:10-319:22. Klitgaard, for instance, describes "[a] limiting mechanism which prevents the setting of a dose, which exceeds the amount of liquid left in a cartridge of an injection device." DTX-2284 at Abstract. The mechanism includes a nut member 32, which is screwed along a helical track 33 on a driver 31 when a dose setting member 30 is rotated relative to the driver. *Id.* at 4:23-32, FIG. 3. Klitgaard states "[t]his way the position of the nut member 32 on the driver 31 will always indicate the total sum of set and injected doses." *Id.* at 4:52-54. When the nut member 32 reaches the end of the track, a user is prevented from "setting a dose larger than the amount remaining in the cartridge." *Id.* at 4:54-58.

c. Flexpen Renders The Asserted Claims Obvious

123. FlexPen qualifies as prior art to the '844 patent because it was "known or used by others" in the United States before March 3, 2003 (35 U.S.C. 102(a)) and "in public use or on sale" in the United States before March 2, 2003 (35 U.S.C. 102(b)).

124. The evidence establishes FlexPen's use or sales before March 2 or 3, 2003. For example, Novo Nordisk documents state that FlexPen was introduced in 2002 and IMS data shows sales between March 2002 and March 2003. DTX-2865 at MYL_IG01002421 (under heading "The history of Novo Nordisk insulin devices in the United States," FlexPen listed as being "approved for use with NovoLog® (insulin apart [rDNA origin] injection) in 2001"); DTX-2853 at MYL_IG01002352 ("The launch of NovoMix® 30 (NovoLogMix® 70/30 in the US) in the disposable delivery device FlexPen® in late 2002 is underpinning this growth."); DTX-2920 (IMS data at rows 74-75, column J, showing sales of NovoLog FlexPen and NovoLog FlexPen Mix 70/30 of about $2.1 million and $7.8 million between March 2002 and March 2003, respectively); TT at 321:4-322:20; DTX-2854 at SANOFI5_00018252 ("In 2001, . . . Novo Nordisk introduced FlexPen®, a new prefilled pen."); DTX-2863 at MYL_IG01002272, MYL_IG01002274-75 (Novo Nordisk London Stock Exchange report stating "[t]he roll-out of products like . . . FlexPen(R) . . . underpins Novo Nordisk's expectations of a positive sales development in 2002.").

125. Dr. Slocum's spreadsheet was based on FlexPen dimensions Dr. Slocum obtained from Mr. Veasey. TT at 546:15-17; *see also, e.g.*, 547:25-548:21; *see generally* TT at 546:15-550:11, 551:7-552:1; TT at 39:2-8 (DCA obtained and measured a FlexPen), 462:9-15 (Dr. Slocum received measurements from Mr. Veasey, who had measured dimensions of FlexPen).

126. While Sanofi attempted to impeach Mr. Leinsing's testimony regarding his personal knowledge of having seen a FlexPen device in 2002 (*see* TT at 323:3-15), Mr.

Leinsing clarified his previous testimony of having "first become aware" of "FlexPen®, the original" two years ago. TT at 329:22-330:5. As Mr. Leinsing acknowledged, two years ago, he was retained as an expert in a litigation involving the Next Generation FlexPen, which involved its comparison to the "original" FlexPen. TT at 330:21-331:15. Mr. Leinsing explained that it was during this litigation where he became aware that there ever was an "original" FlexPen and came to "understand[] what the difference was between [the] original and Next Generation." TT at 330:8-14 ("I didn't even know when I was looking at that pen back then whether that one was original or not with the name."), 330:25-331:1 ("Yes. That's when I became aware of there being a Next Generation and an original FlexPen®."). Mr. Leinsing's testimony that he "had in [his] hands" a FlexPen device before 2003 is thus consistent with his previous testimony of learning that there was an "original" and a "Next Generation" two years ago.

127. Mr. Veasey, moreover, testified that DCA documents showing the FlexPen accurately represent the prior art device that was available prior to March 2003, because DCA engineers had used a FlexPen sample as the basis for their CAD drawings and other analysis. TT at 64:2-67:4; *see also* DTX-2268 (DCA document showing component details and proposed assembly sequence); PTX-220 (DCA document of FlexPen analysis). Mr. Veasey's testimony also reflects the fact that artisans working in the injector pen field in 2002 (before the priority date of the '844 patent) were able to obtain a FlexPen sample if they desired one. TT at 38:11-39:1 (Mr. Veasey stating that Aventis (Sanofi) provided a FlexPen sample to DCA).

128. Sanofi stipulated that the FlexPen discloses all of the same elements of the asserted claims that are disclosed by Steenfeldt-Jensen, which covered most limitations in claim 21 and all of the additional limitations in claims 23-25. ECF No. 529 at 4-6. Sanofi further stipulated that FlexPen discloses claim 30. *See id*. Sanofi thus only contested that FlexPen

disclosed the limitations associated with threading on the driving member in claim 21. TT at 320:5-17.

129. On direct examination, Dr. Slocum agreed that, for the purposes of obviousness, there is no difference between Steenfeldt-Jensen's fifth embodiment and the FlexPen. TT at 451:19-22.

130. As discussed above, Steenfeldt-Jensen and Chanoch render the asserted claims obvious, and the POSA would implement the alternative described in Steenfeldt-Jensen in FlexPen (and Dr. Slocum failed to state any reasons to the contrary). *See* Section II.B.1.b., *supra*; TT at 451:19-22 (Dr. Slocum admitting that for purposes of claim 21, there is no difference between Steenfeldt-Jensen and FlexPen); *see generally* TT at 451:19-465:22; *id.* at 471:20-485:4 (Dr. Slocum failing to cite reasons POSA would not implement a threaded driver in FlexPen aside from those raised with respect to Steenfeldt-Jensen).

131. As a result, FlexPen, viewed in light of the prior art, also renders obvious all asserted claims.

d. Giambattista Renders The Asserted Claims Obvious

132. Sanofi agrees that Giambattista describes a pen injector that meets each and every one of the limitations recited in claim 21, except "a piston rod holder that is rotatably fixed relative to the housing." *See* ECF No. 529 at 4-6; TT at 324:12-24.

133. Giambattista discloses an injector pen that can be reusable instead of disposable. *See* DTX-2283 at 1:5-7 (stating generally that "[t]he present invention relates to a medication delivery pen having a variety of features and, more particularly, a low-cost medication delivery pen having very few parts"), 2:29-50 (describing a mechanism that "allows the user to easily load a new vial and reposition the lead screw"). The pen described in Giambattista includes "retract nut 4," which engages with and holds the piston rod. *Id.* at 3:39-43, FIG. 4.

Giambattista explains that retract nut 4 is held in place during pen operation by the vial retainer 2. *Id.* at 3:47-51, 4:13-21. Retract nut 4 has splines that prevent rotation of the lead screw when the device is used. *Id.* at 3:36-51, 3:59-64, FIG. 4. As a result, the "retract nut 4" expressly disclosed by Giambattista satisfies the requirement in claim 21 for a piston rod holder that is rotatably fixed to the housing.

134. Although retract nut 4 may rotate if the user replaces an empty cartridge with a new, full, cartridge, in which case the retract nut rotates to allow the user to push the piston rod back into the housing and reset its position (TT at 486:2-14; DTX-2283 at 3:51-54), the POSA would understand that retract nut is rotationally fixed to the housing at all other times, and the vast majority of the time overall. *See* DTX-2283 at Abstract, 3:3-5 (stating "FIG. 9" as showing the medication delivery pen "fully assembled" with vial retainer 2 attached), 3:47-51, FIG. 9.

135. Moreover, the claims of the '844 patent do not require a disposable pen nor preclude a reusable pen, and the specification of the '844 patent does not, either. *See* JTX-3 at Abstract ("The present invention relates to injectors, such as pen-type injectors . . . ."), 1:25-43, claim 21 (claiming "[a] drug delivery device").

136. Further, the only phases of operation described in the '844 patent are dose setting (including dose correction) and dose dispensing. *See, e.g.*, JTX-3 at 5:54-6:67, claim 21. The retract nut in Giambattista is rotatably fixed to the housing during both of those phases of operation. TT at 325:12-326:2, 565:3-23 (Dr. Slocum admitting that when device is "being used to act as a drug delivery device to inject medicament," retract nut 4 is rotatably fixed, and when user is replacing a vial, device is "not operational to inject insulin"), 569:8-15.

137. And even if the claim precluded a reusable device that allows a user to replace a spent cartridge, it would have been obvious to permanently affix the "piston rod holder" in

Giambattista's device if a POSA were inclined to design a single-use (disposable) device. TT at 569:22-570:6. Notably, claim 1 of Giambattista does not preclude a disposable device. DTX-2283, claim 1 (claiming "[a] medication delivery pen"). It is only in claims 6 and 7, which depend from claim 1, that a reusable pen is specifically claimed. *Id.* at claims 6-7 (claiming "a reload mechanism" having "a retract nut that "allow[s] a user to reload said medication delivery pen").

138. Giambattista renders claim 22 obvious because it discloses a leadscrew (i.e., piston rod) with circular cross-sections. TT at 326:5-11; DTX-2283 at FIG. 1.

139. As with Steenfeldt-Jensen and Chanoch, although Giambattista describes a piston rod having "flat sides" along a portion of its length, other portions of the piston rod, like its ends, include circular cross-sections. TT at 326:5-11, 570:17-21; *see also* Section II.B.1.b.ii., *supra*.

2. Secondary Considerations Do Not Rescue The '844 Patent

140. Defendants established a strong *prima facie* case of obviousness and Sanofi's alleged objective indicia or "secondary considerations" do not overcome the obviousness of the '844 patent due to inherent weaknesses, lacking nexus, and reflecting improper hindsight, and in sum being insufficient to overcome the strength of the obviousness case.

141. Sanofi did not offer evidence of secondary considerations such as licensing, copying, failure of others, unexpected results, unexpected properties, or skepticism from skilled artisans. *See generally, e.g.*, TT at 189:18-25. Thus, those considerations do not support obviousness.

142. Sanofi did not offer evidence of secondary considerations for claim 22, either. Sanofi presented alleged secondary considerations as to claims 21, 25, and 30 only, because Sanofi's Lantus SoloSTAR does not practice that claim. *See, e.g.*, TT at 194:7-9 ("Q. How did you conclude that there was a nexus between the commercial success of SoloSTAR and the ***three***

claims of the '844 patent?") (emphasis added), 516:11-17 (presenting evidence with respect only to claims 21, 25, and 30); *see also id.* at 516:22-517:2 (discussing analysis of whether the SoloSTAR practices claims 21, 25, and 30, without reference to claim 22).

143. Instead, Sanofi asserted only that 1) a long-felt but unresolved need; 2) commercial success; and 3) industry praise allegedly support inferring nonobviousness of claims 21, 25, and 30. None support nonobviousness.

a. There Is No Nexus To The Alleged Commercial Success

144. Sanofi contends that its Lantus SoloSTAR pen was commercially successful due to the claimed features of the '844 patent. TT at 189:22-25. Here, Sanofi has failed to establish a nexus between the claims of the '844 patent and sales of Lantus SoloSTAR. TT at 208:15-210:4, 405:13-406:3, 412:5-7, 417:9-14, 423:24-424:17; DTX-2637 at SANOFI_00560111.

145. Instead, Sanofi's purported evidence of commercial success of the Lantus SoloSTAR is the result of marketing (*see, e.g.*, TT at 211:16-23, 217:14-23, 408:11-409:13; *see generally* DTX-2661; DTX-2631), the unclaimed drug formulation (*see, e.g.*, TT at 207:17-208:14, 210:15-25 (noting that, in addition to the '844 patent, "sales are attributed to the insulin in the . . . SoloStar.")), and unclaimed design features (*see, e.g.*, TT at 212:6-213:7; PTX-720 at SANOFI3_90330845; *see also* TT at 199:8-19).

146. Regarding unclaimed design features, for example, Dr. Slocum testified that the "collapsing thread[s]"—the two, opposing threads on the piston rod—give rise to the alleged high efficiency of the pen in the '844 patent. TT at 518:2-13. Likewise, Mr. Veasey said that the interaction of the piston rod being threaded to the insert and threaded to the drive sleeve (along with a clutch) gives rise to "high efficiency force transfer to allow a low injection force." TT at 35:11-25. The asserted claims do not require "collapsing threads" on the piston rod, however, and therefore omit a key feature of the pen described in the '844 patent.

147. As a result, for the foregoing reasons Sanofi's evidence of commercial success does not support an inference of nonobviousness. *See, e.g.*, TT at 419:3-9 ("So what the Levemir experience shows is that when you change the pen, you have no observable impact. But when you change the insulin, you have a very clear observable impact.").

148. For example, the overall prescription rate of Lantus from 2002-2019 shows that after the introduction of the Lantus SoloSTAR, the overall prescription growth rate of Lantus decreased relative to the trajectory that existed prior to the introduction of the Lantus SoloSTAR. TT at 410:20-411:19 (referencing data in DTX-2541 and DTX-2920). If SoloSTAR truly drove commercial success, then sales, or the rate of sales growth, should have increased when the SoloSTAR was introduced to the market. *See, e.g.*, TT at 410:15-411:19; DTX-2637 at SANOFI_00560111; DTX-2541; DTX-2920; *see also* TT at 406:19-408:8. The proper focus is on the incremental impact the SoloSTAR made on the market. TT at 409:16-25.

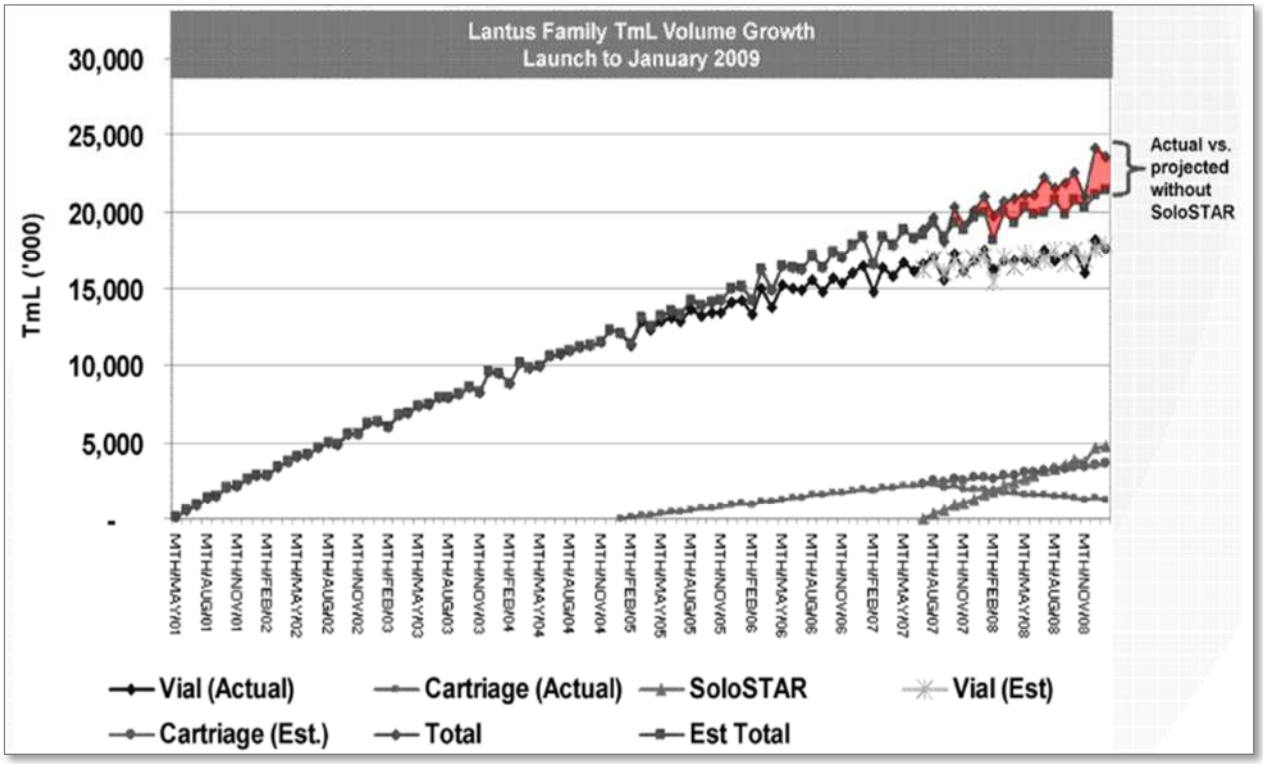
149. Sanofi's evidence, however, shows that sales were driven by Sanofi's dominant position in the insulin glargine market—a position owed in large part to two blocking patents on insulin glargine.[2] *See, e.g.*, TT at 208:15-210:4, 408:11-409:13, 419:3-9; DTX-2637 at SANOFI_00560111; TT at 420:7-424: 23; *see also* DTX-2625, DTX-2581.

150. Dr. McDuff explained that DTX-2625, "FTO (Freedom to Operate) in the Pharmaceutical Industry," teaches that "hen companies are considering what products to pursue, they are aware of what patents are out there and they want to avoid infringement and look for opportunities where there's freedom to operate." TT at 421:23-422:4 (describing DTX-2625).

[2] Sanofi also asserted two Orange Book-listed formulation patents in this litigation, U.S. Patent Nos. 7,476,652 ("the '652 patent") and 7,713,930 ("the '930 patent"). *See* ECF No. 1 at ¶¶ 1, 66-67, 86.

151. DTX-2581, a paper by Correa, explains that "[w]hen the innovation process is cumulative, strong protection for the first-generation producer limits the scope of second-generation producers, and slows down follow-on innovation." DTX-2581 at MYL_IG00993439.

152. The SoloSTAR "had a relatively modest impact" on Sanofi's sales of insulin glargine. TT at 410:1-14. Indeed, as of March 2009, Sanofi's own documentation shows that overall sales of the Lantus franchise were hardly higher at all when comparing actual sales, including SoloSTAR, with projected sales had SoloSTAR not launched. DTX-2637 at SANOFI_00560110-111. The graph below shows that Sanofi hardly attributed few additional sales to SoloSTAR.



Id. at SANOFI_00560111 (annotation added).

153. Sanofi has also used patents to control the insulin glargine industry, even listing 23 patents in the FDA orange books from 2000 to 2019 as relating to the Lantus products. TT at

412:13-22. Sanofi's blocking patents claim priority back to 1988, with the '722 patent and the '376 patent issuing in 1997 and 2000, which expired in 2009 and 2014. TT at 422:21-23.

154. The relevant timepoint when assessing blocking patents, is leading up to the alleged priority date of the '844 patent in 2003. TT at 420:7-18.

155. From 2001 onwards, Sanofi had the exclusive opportunity to pursue market opportunity to sell a pen containing insulin glargine because of the '722 and '376 blocking patents that blocked the rest of the market from developing an injector pen like SoloSTAR or the pen described in the claims of the '844 patent. TT at 422:21-423:6.

156. Competitor products that didn't come onto the market until after the insulin glargine patents expired further demonstrate that the insulin glargine was blocked during the relevant time period. TT at 423:7-13.

157. While the '844 patent does not relate specifically to insulin glargine, the sharp difference in market success between Sanofi's products with and without insulin glargine demonstrates that the commercial opportunity was for the insulin, which was blocked by Sanofi's patents. TT at 423:16-424:17.

158. Sanofi relied on sales of Lantus SoloSTAR as alleged commercial success, but Sanofi's blocking patents meant that only Sanofi could take advantage of the market opportunity for insulin glargine during the relevant time period. Sanofi's blocking patents provided a strong disincentive for the rest of the market, which was blocked from developing "the '844 patent or anything related to SoloStar." TT at 422:19-423:6; 424:18-23. As a result, the presence of blocking patents precludes any inference of nonobviousness of the '844 patent. *Id.*

159. Indeed, Sanofi's own documents show that the focus for driving sales was the insulin formulation inside the SoloSTAR, not the pen itself. *See, e.g.*, DTX-2661 at

SANOFI_00232916, SANOFI_00232923, SANOFI_00232929-930; DTX-2631 at SANOFI_00201517; DTX-2637 at SANOFI_00560111; TT at 174:5-15; 408:11-410:14, 419:3-9, 423:16-424:17 ("[T]he commercial opportunity for insulin was the primary commercial opportunity, which is that [which] would be blocked by the insulin glargine patents.").

160. The data also shows that the force behind sales of Lantus SoloSTAR was the insulin glargine, not the pen. Dr. McDuff examined market share, in which Lantus SoloSTAR had 21.6 percent, Toujeo SoloSTAR had 4.1, Admelog (SoloSTAR) had 0.6 percent, Apidra SoloSTAR had 0.5 percent, and Soliqua (SoloSTAR) had 0.5 percent. TT at 423:22-424:8. Based on this data, the relevant commercial opportunity was for the insulin, not for the pen. *Id*. at 424:9-17.

161. Lastly, even if Sanofi claims that a lower injection force helped drive sales, claim 21 of the '844 patent does not require or guarantee any specific injection force. *See* JTX-3 at 8:16-49. Indeed, Mr. Veasey admitted that claim 21 includes pens with high injection force. TT at 81:9-17.

162. Sanofi also claimed that Lantus SoloSTAR helped drive sales because of low injection force and ease of use. Those attributes are not claimed by the '844 patent. JTX-3 at 8:16-49. Moreover, Dr. Slocum explained that the high efficiency and low injection force of the SoloSTAR results from "collapsing thread" piston rod described in the '844 patent. TT at 518:2-519:1; *see also* TT at 281:15-18; JTX-3 at 4:3-9; TT at 35:7-25. None of the asserted claims require a dual-threaded piston rod (i.e., with collapsing threads), however, so even if there were sales driven by SoloSTAR, the sales do not support nonobviousness because they would result only from unclaimed features. JTX-3 at claims 21, 22, 25, 30.

b. The '844 Patent Did Not Fulfill A "Long-Felt But Unmet Need"

163. There was no long-felt but unmet need for the Lantus SoloSTAR pen.

164. In 2008, when the SoloSTAR pen was introduced, there were other pens available on the market that patients were able to use to deliver insulin, including the Next Generation FlexPen, which Dr. Slocum admitted that it had a low injection force. TT at 373:17-22; TT at 592:18-21; *see also* PTX-661 at SANOFI_00287776. Other pens available as of 1999 also incorporated desirable features and were "easy to use." TT at 372:17-373:16; DTX-2084. Furthermore, patients could operate pens available before the '844 patent using a similar injection force as required to operate the SoloSTAR. TT at 375:18-376:4, 376:16-377:3.

165. Sanofi nevertheless sought to establish, through Dr. Goland's testimony, that prior to March 2003 there was a long-felt but unmet need for an easy-to-use, easy to dial, discreet, disposable insulin pen with a low injection force, easy-to-read dose indicator, and 80-unit dosing capability. TT at 158:23-159:2, 162:19-24, 170:9-17. These features conspicuously reflect promotional materials for the SoloSTAR. *See* DTX-2661 at SANOFI_00232923 ("[e]asy to teach"; "[e]asy to use"; "[e]asy to inject," with core features of "1 to 80 units in 1 unit steps'; "[e]asy to set the dose – can dial up and down"; "[e]asy to read dose numbers"; "[e]asy to differentiate.").

166. Moreover, these features were already available in other pens, as explained by Dr. Biggs. TT at 372:17-373:16; DTX-2084 at MYL_IG00992055-056. The '844 patent does not claim any specific injection force, a low injection force, or an allegedly superior ease of use. *See* JTX-3 at 8:16-59, 9:8-10; TT at 81:9-17, 593:11-14. Dr. Goland was unable to identify any particular need in the industry met by the claimed features of the SoloSTAR, as she did not have

knowledge of the claim scope. *See* TT at 173:2-10. Indeed, Dr. Goland admitted she "never reviewed the patent." TT at 172:11-18.

167. Dr. Goland's lack of knowledge relating to the patent claims resulted in multiple flaws in her analysis, such as the understanding—obtained from Dr. Slocum—that "low injection force was, in fact, one of the claims of the patent." TT at 172:19-24. In fact, Dr. Goland testified that the insulin glargine peptide, which is not covered by any claim of the '844 patent, met a long-felt, unmet need. TT at 173:11-18.

168. Sanofi's own SoloSTAR Launch Book reinforces the idea that the type of insulin is they key variable. *See, e.g.*, DTX-2661 at SANOFI_00232930 ("Other traps to avoid . . . Selling the pen without selling the insulin . . . our long term advantage comes from the insulin properties.") (emphasis omitted). Because Lantus is not available in any pen injector, SoloSTAR is the only option where a doctor wishes to prescribe Lantus in a pen form, as opposed to vial and syringe. TT at 175:20-176:2, 374:11-14. Shortly after the SoloSTAR was introduced, Sanofi undertook marketing efforts to incentivize converting vial prescriptions into SoloSTAR prescriptions. TT at 380:5-22; DTX-2661 at SANOFI_00232916.

169. Sanofi's Launch Book also directly contradicts Sanofi's argument that there was any long-felt but unmet need. For example, the SoloSTAR Launch Book describes common objections that SoloSTAR sales professional were expected to encounter, including, "Why is injection force important / My patients don't have trouble with injections." DTX-2661 at SANOFI_00232930. The Launch Book further shows that injection force is inherently tied to unclaimed features such as needle gauge and length, brand of needle, insulin choice, and speed of injection. *Id.* at SANOFI_00232932 (describing the effect of various factors on injection force in section titled "Important things to know"); *see also* TT at 376:16-24 (noting that

injection force is not an issue for patient adherence because a longer injection can be used to lower the force required to inject).

170. As Dr. Biggs explained, because the SoloSTAR is substantially the same as other injector pens, if a patient has difficulty operating one injection pen due to infirmities, they will face the same difficulty with the SoloSTAR, and therefore require a different treatment modality altogether; the Lantus SoloSTAR has not met any long-felt need with respect to improving access to self-injection of insulin. TT at 377:4-19.

171. Comparing the success of SoloSTAR to Sanofi's OptiClik pen does not demonstrate a long-felt but unmet need because OptiClik had "many issues," including that "[p]eople complained it was inaccurate," it could be described as inaccurate, it "was not a good insulin pen," "didn't deliver accurately," was "big," and "the numbers were hard to read." TT at 171:7-23; *see also* 373:23-374:20.

c. Sanofi's Self-Funded Industry Praise Does Not Support Nonobviousness

172. Sanofi's evidence of alleged industry awards does not demonstrate industry praise and is insufficient to rebut obviousness. Dr. McDuff testified that the awards focus on the Lantus SoloSTAR generally, and are not specific to the '844 patent's claimed features. *See* TT at 419:18-20.

173. Regarding the alleged Good Design Award, neither Mr. Veasey nor Dr. Grabowski described the criteria allegedly used to determine who should receive the award, what other pens, if any, were candidates, or why the Chicago Museum of Art and Science chose the SoloSTAR pen. TT at 61:7-13; *id.* at 202:13-18. The document relied upon by Dr. Grabowski, moreover, is a DCA press release. PTX-864. As a result, the language Dr. Grabowski relied upon regarding "leading performance" was language written by DCA or Sanofi, not the awarding

agency. *See* TT at 202:23-203:9. Moreover, PTX-864 does not describe any analysis of the claims of the '844 patent; instead, it only cites the SoloSTAR pen generally. *See generally* PTX-864. Further, along with Sanofi, there were 30 pages of other award winners, including 16 other award winners in the medical category. TT at 217:14-23. As a result, the Good Design Award is not "industry praise" of the claimed invention nor does it support an inference of nonobviousness.

174. Likewise, regarding the Design Business Association award, neither Mr. Veasey nor Dr. Grabowski described the criteria allegedly used to determine who should receive the award, what other pens, if any, were candidates, or why the DBA granted the award. TT at 61:7-20, 62:13-22, 203:13-204:3. Instead, Mr. Veasey testified that DCA or Sanofi submitted an application requesting the award and paid a fee that could have been £1,000. TT at 82:8-83:2. The press release cited by Sanofi, fails to describe any analysis of the claims of the '844 patent and neither Mr. Veasey nor Dr. Grabowski established a nexus between the award and the claims of the '844 patent sufficient to demonstrate industry praise of the claimed invention. *See generally* PTX-1588; TT at 61:7-20, 62:13-22, 203:13-204:3.[3]

3. The '844 Patent Is Invalid Under Section 112

175. The '844 patent is also invalid pursuant to 35 U.S.C. § 112 for lacking adequate written description and failing to enable the full scope of the asserted claims. *See, e.g.*, TT at 326:20-327:7.

[3] Dr. Grabowski also described PTX-461 as the "basis for winning the award," but he did not testify regarding any foundation or basis for knowing that alleged fact. TT at 204:4-13. And the document itself does not reference the claims of the '844 patent. *See* PTX-461. As a result, Dr. Grabowski's testimony and the exhibit have little, if any, probative value regarding alleged industry praise.

176. First, the '844 patent does not describe or enable embodiments having an internally threaded piston rod, (*see, e.g.*, TT at 285:19-286:8, 290:4-7, 292:10-24), and second, to the extent the lone embodiment in the patent has a piston rod "holder," that holder is not configured to prevent rotation during dose setting (*see, e.g.*, TT at 293:15-294:24). Notably, the alleged "piston rod holder" in the '844 patent, insert 16, could only hold an externally-threaded piston rod. There is no disclosure in the '844 patent for how to hold an internally-threaded piston rod in its proper position, nor is there disclosure in the '844 patent for how to hold an internally-threaded piston rod against rotation during dose setting. *See generally* JTX-3.

177. Sanofi approached DCA to design an injector pen in 2001. TT at 36:3-7; *see also id.* at 64:2-9. DCA's work to develop different design concepts occurred in 2002. TT at 50:24-51:8, 51:19-22; *see also* DTX-2921, Schwarz Depo, at 19:16-20 (Project Alpha began in 2002).

178. The '844 patent's § 112 problems arise out of Sanofi's attempt to take patent protection intended to cover the inventors' work from the 2002-2003 time period, and stretch this patent protection to include the Proposed Pen, which was independently developed by BD. *See* TT at 36:14-21, 52:19-21, 57:1-24, 224:11-19; *see also* DTX-2850 (Sanofi's 2003 patent application filed in Great Britain).

179. The patent application to which the '844 claims priority was filed in the UK on March 3, 2003, and the US application was filed March 2, 2004. JTX-3 at (30), (60). As explained by Mr. Veasey, a named inventor of the '844 patent and employee of DCA, the application was intended to cover "Concept 12," one of DCA's design concepts. TT at 52:19-21.

180. In the ensuing years, from 2004 to 2016, Sanofi filed over a dozen and close to twenty other related applications, but there is no evidence that any of them disclosed or claimed an internally threaded piston rod or a piston rod holder. *See, e.g.*, JTX-3 at (60), 1:6-21; *see also*

TT at 79:18-24 (describing "separate lines of patents" filed on "several" DCA concepts), 283:9-284:4 (discussing the '844 patent family tree); *see also, e.g.,* ECF 1-1, ¶¶1, Exs. A-R (disclosing sixteen device patents that Sanofi filed relating to SoloSTAR and describing the assertion of two formulation and sixteen device patents).

181. In February 2014, a patent application describing BD's new pen was published, describing a hollow plunger rod with internal threads. *See, e.g.*, DTX-2291 at (43), ¶ [0006], Fig.52 (item 606); TT at 253:5-16.

182. By 2015, it was public knowledge that BD's new pen was being used for Biocon's insulin glargine product outside the US. DTX-2921, Bode Depo, at 124:9-20, 124:23-125:3, 125:5-7; DTX-2015; DTX-2016. Only then, in May 2016, *after* publication of BD's applications disclosing an internally threaded piston rod, did Sanofi file an application with claims reciting an internally threaded piston rod. JTX-3 at (22). Thus, the application that led to the '844 patent was filed over 13 years after the purported invention and after the first patent application was filed on the subject matter of the '844 patent. JTX-3 at (22), (30). Notably, Sanofi filed the application that led to the '844 patent on May 17, 2016 and the '844 patent issued only about seven months later, on December 27, 2016. JTX-3 at (22), (45).

a. The '844 Patent Lacks Support For Claims Directed To An Internally-Threaded Piston Rod

183. Claim 21 recites "a piston rod comprising either an internal or an external fourth thread." JTX-3 at 8:16-49. Claim 21 also requires a "driving member comprising a third thread," where the third thread engages with the fourth thread of the piston rod. *Id.* But, as Mr. Leinsing explained, there is no description in the '844 patent of either an internally threaded piston rod or an externally threaded driving member. *See generally* JTX-3; TT at 283:11-286:8, 290:4-7. The sole embodiment disclosed in the specification to the '844 patent has an externally

threaded piston rod that engages with the internal threads located on the drive sleeve. TT at 285:19-22; *see generally* JTX-3; TT at 586:3-7.

184. There is no explicit or implicit suggestion in the specification that the piston rod could instead somehow be configured have internal threads, nor any explanation for how one might modify other components in the device to accommodate such a change. TT at 285:19-286:8. Likewise, there is no description of a "driving member" having external threads that engage with internal threads of the piston rod. TT at 285:19-22; *see generally* JTX-3. The only external threads on the drive sleeve 30 engage with internal threads on nut 40. JTX-3 at 4:18-31, 6:14-21, Fig. 13. There is also no description of external threads on drive sleeve 30 that engage with a piston rod. *See generally* JTX-3.

185. The '844 patent also describes several components as hollow or internally-threaded components, such as the dose dial sleeve, clutch, clicker, housing, and insert. *See* JTX-3 at Abstract, 2:1-4, 2:30-35, 3:62-64, 4:13-14, 4:20-21, 4:29-31. But there is no statement in the specification that the piston rod could be hollow. *See generally* JTX-3. Instead, the only description in the '844 patent of (1) an internally-threaded piston rod or (2) external drive sleeve threads that engage with a piston rod is found in claim 21. JTX-3 at 8:16-49. Sanofi's expert, Dr. Slocum, agrees that the '844 patent does not depict an embodiment having an internally-threaded piston rod. TT at 586:3-7. Moreover, the '844 patent uses "sleeve" to describe hollow or tubular components and "rod" to describe solid components (such as the piston rod of claim 21). *See* TT at 138:1-4; JTX-3 at Abstract, 1:53-2:4, 2:30-35, 3:62-64, 4:13-14, 4:20-21, Figs. 1-4, 9-11.

186. The disclosure of the '844 patent therefore fails to establish or even suggest to the POSA that the inventors possessed an internally-threaded piston rod or external drive sleeve

threads that engage with a piston rod as of March 3, 2003. TT at 285:19-286:8, 290:4-7, 292:10-24. The POSA would not infer that the inventors possessed or enabled an internally threaded piston rod. TT at 285:19-286:8, 290:4-7, 292:10-24. In fact, neither internally-threaded piston rods nor externally-threaded driving members were known in the prior art injector pens. TT at 285:19-286:8, 290:4-7, 292:10-24. Indeed, the face of the '844 patent lists about 200 references, (JTX-3 at (56)), yet Sanofi's expert Dr. Slocum was unable to identify ***any*** prior art describing an injector pen piston rod with internal threads. TT at 586:2-587:5. Instead, Dr. Slocum cited two patents that were provided to him by counsel and that only relate to motorized pumps. TT at 500:19-21 (admitting on direct that they do not disclose pen injectors); TT at 586:2-587:8; PTX-638; PTX-640.

187. Spinello (PTX-640) describes a motorized device for injecting anesthetic. PTX-640 at (54), Abstract, Fig. 5 (citing a motor driver circuit), 6:28-36. Spinello's claims are directed to methods for anesthetizing body tissue with a "uniform flow of anesthetic." *Id.* at claims 1-4. Spinello does not describe an injector pen. *See generally id.*

188. Kamen (PTX-638) describes an infusion pump and refers to a "piston member," but not a piston rod. PTX-638 at (54), Abstract; *see also id.* at claim 1 (claiming a "volumetric pump"). Kamen does not describe an injector pen. *See generally id.*

189. Dr. Slocum stated, in conclusory fashion, that these patents describe "drug delivery device[s]," but he failed to come forward with any evidence as to why the POSA would consider them pertinent prior art or how the POSA could possibly implement any teachings from them into the embodiment of the '844 patent.

190. There is no evidence establishing that the POSA would have looked to motorized pump prior art in 2003. Dr. Slocum's direct testimony provides conclusory statements that

internally-threaded piston rods and external driver threads engaged with a piston rod was "known in the prior art," (*see, e.g.*, TT at 498:22-25), but no basis is given to suggest that a POSA would have looked to the references cited (*see generally* TT at 498:22-501:3). Dr. Slocum stated that the references are "all in the same field for injecting medicaments into people," (TT at 501:2-3), but that is not sufficient to establish that a POSA would look to the references when designing an injector pen. As a result, the references identified by Dr. Slocum (*see* PTX-638; PTX-640) are inapposite and would not cause a POSA to infer possession of an internally threaded piston rod when the '844 patent itself—and the hundreds of patents cited on the '844 patent—do not disclose an internally threaded piston rod.

191. Sanofi nevertheless argues that the scope of claim 21 properly includes "internally threaded piston rods" because of generic statements in the '844 patent. TT at 494:11-495:17. According to Dr. Slocum, there are only two ways a POSA could thread a piston rod, internal or external, so a POSA would understand that an internally threaded piston rod was one of the options. TT at 494:11-495:17. To illustrate the internally threaded option, Dr. Slocum drew a variation to the embodiment in the '844 patent having an internally threaded piston rod that engaged with a "stinger" added to the drive sleeve. *See* DTX-2846.

192. There is no basis to credit Dr. Slocum's testimony regarding a POSA's purported knowledge that a "stinger" arrangement could be used. The fact that Sanofi's counsel could not find a single injector pen with an internally threaded piston rod in the prior art betrays Sanofi's claim that a POSA would readily understand the '844 patent as implicitly disclosing one. *See* TT at 498:22-501:3. In fact, Dr. Slocum admitted that the two references he identifies contain motors, and that motors are not present in the injector pens at issue here. TT at 586:8-587:1. Further, he did not search for any internally-threaded piston rods in injector pens as of the

priority date. TT at 587:2-8. Further, Dr. Slocum's spreadsheet showed that if standard Delrin plastic was used, the "stinger" would buckle. DTX-2925 at 1 (showing, at the bottom of the page, "YES" for buckling for "*Shaft with flats*" and "*Shaft without flats*"); TT at 578:14-579:1, 579:14-580:24, 581:19-582:9. Only if the material was changed to a more-expensive, exotic plastic, which Dr. Slocum described as "Vectra" (*e.g.*, Kevlar), would Dr. Slocum's spreadsheet not show buckling, but there is no evidence in the record regarding use of Vectra in any injector pen. DTX-2926; TT at 582:17-583:1, 585:9-12.

193. Dr. Slocum's direct testimony that a pen injector is a "precision machine" (TT at 442:18-24) is at odds with the idea—implied or otherwise—that design considerations for motorized pumps would be the same as for the (motor-less) injector pen taught by the '844 patent. As Mr. Leinsing explained, implementing an internally threaded piston rod to the embodiment in the '844 patent would cause manufacturing problems and increase costs due to the amount of detail required in designing an injector pen. TT at 286:23-287:11, 289:10-290:3; *see also* DTX-2921, Perkins Depo., at 114:8-12, 114:14-20, 114:22-115:6, 115:8-12. As a result, Dr. Slocum's suggested "stinger" is contrary to the specification's express goals that the injector pen be "robust in construction" and "cheap to manufacture." JTX-3 at 1:36-37, 42; TT at 286:23-288:6, 289:5-290:3.

194. Lastly, Dr. Slocum's testimony regarding a POSA's understanding in 2003 should not be credited when he lacked any experience with injector pens at that time and gained all of his knowledge from that time from named inventor and Sanofi witness Robert Veasey. TT at 521:8-524:18.

195. Defendants have thus shown by clear and convincing evidence that a POSA at the time of filing the application to which the '844 patent claims priority would not have understood

the inventors to possess an injector pen with an internally-threaded piston rod, nor an externally-threaded driving member. As a result, claim 21 is invalid for lack of written description.

196. Defendants have also shown by clear and convincing evidence that claim 21 is invalid as not enabled. The '844 provides no instruction whatsoever for how to make and use an injector pen having an internally threaded piston rod with an externally threaded driver. TT at 285:19-286:8, 290:4-7, 292:10-24, 586:3-7; *see generally* JTX-3. Named inventor Robert Perkins testified that redesigning the externally threaded piston rod to have internal threading would require making additional changes to multiple other components to have "a theoretically functional design" because "it's part of a complex system." DTX-2921, Perkins Depo., at 114:8-12, 114:14-20, 114:22-115:6, 115:8-12.

197. Mr. Leinsing also explained that redesigning the pen to have an internally threaded piston rod and externally threaded driving member would result in a pen with a larger diameter, would be difficult to manufacture, and would take considerable time and experimentation to develop. TT at 283:11-286:8, 286:23-288:6, 289:5-290:7.

198. With nothing in the specification as a guide, the POSA—which Dr. Slocum opined could be a recent college graduate with no injector pen experience (TT at 446:8-18)—would not have been able to modify the disclosure in the '844 patent to make and use a pen with an internally threaded piston rod and externally threaded driving member without undue experimentation and claim 21 (and all claims depending therefrom) are invalid for lack of enablement.

b. The '844 Patent Lacks Support For A Piston Rod Holder Configured To Prevent Rotation During Dose Setting

199. Claim 21 also requires a "a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii)

permit the piston rod to traverse axially towards the distal end during dose dispensing." JTX-3 at 8:16-49.

200. There is not sufficient support for the claimed piston rod holder that is configured to prevent rotation during dose setting. TT at 293:15-294:24, 577:18-578:3. The '844 patent does not mention a "piston rod holder" except for in the claims. TT at 293:15-294:24, 577:18-578:3. As a result, there is no express description for a holder that is "configured to prevent" rotation during dose setting as required by claim 21. TT at 293:16-17; *see generally* JTX-3.

201. Sanofi's expert, Dr. Slocum, nevertheless contended that insert 16 corresponds to the claimed "holder" because, if insert 16 were not present, the piston rod could rotate during dose setting. *See* TT at 514:13-515:3. Dr. Slocum testified that, without the insert, the piston rod could rotate, (*see* TT at 513:7-9), but he only assessed whether rotation could occur, not whether the design of the insert was "configured" to prevent rotation. *See generally* TT at 513:4-515:3.

202. Insert 16 does not support the full scope of claim 21 because the specification describes the *piston rod*'s design as preventing rotation, not insert 16. JTX-3 at 6:11-13 ("Rotation of the piston rod 20 is prevented due to the opposing directions of the overhauled and driven threads on the piston rod 20."); TT at 512:17-24, 514:16-19. In fact, insert 16 is configured to ***allow*** rotation of the piston rod through its threaded bore. JTX-3 at 6:55-58.

203. Thus, a POSA would not have understood the inventors to have been in possession of the claimed "holder."

204. As a result, there is no written description support for a "piston rod holder" that is configured to prevent the piston rod from rotating during dose setting.

205. Claim 21 is also invalid for lack of enablement because the specification does not enable the full scope of the claim. Claim 21 is written with functional words, such as "holder" (i.e., a thing that "holds") and "configured to prevent rotation" (i.e., language directed to an outcome, not structure). JTX-3 at claim 21.

206. The Court's claim construction Order did not adopt a means-plus-function construction for the "piston rod holder." ECF No. 319 at 24. Thus, the scope of the claim appears to cover all ways of configuring a "piston rod holder" to prevent rotation of the piston rod during dose setting, including opposing threads, flats, splines, and keys.

207. But the '844 patent does not teach how to prevent rotation of the piston rod during dose setting using flats on the piston rod, splines on the piston rod, or keys on a piston rod. JTX-3 at 6:11-13; *see also* TT at 293:18-294:21. Instead, as claimed, the piston rod holder of claim 21 must be configured to prevent rotation ***during dose setting*** (JTX-3 at 8:16-49) and the only disclosure in the '844 patent of how to configure a component to prevent rotation of the piston rod during dose setting is using oppositely disposed threads. JTX-3 at 6:11-13.

208. As a result, a POSA has no guidance for how to make a piston rod holder with anything other than threads and thus could not make and use the full scope of the claims without undue experimentation. Claim 21 and all claims depending therefrom are therefore invalid for lack of enablement.

PROPOSED CONCLUSIONS OF LAW

I. INTRODUCTION

Pursuant to the Court's Pretrial Order (ECF No. 525), Defendants Mylan GmbH, Biocon Ltd., Biocon Research Ltd., Biocon Sdn. Bhd., and Biocon S.A. ("Defendants") hereby submit the following Proposed Conclusions of Law and a citation of authorities relied upon.

II. CLAIM CONSTRUCTION

1. The starting point for analysis of infringement and invalidity is the asserted claims of the '844 patent. *See, e.g.*, *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1581-82 (Fed. Cir. 1996); *National Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1334 (Fed. Cir. 2004). Claims are construed the same way for both infringement and invalidity. *TVIIM, LLC v. McAfee, Inc.*, 851 F.3d 1356, 1362 (Fed. Cir. 2017).

2. The words of a claim "are generally given their ordinary and customary meaning," but each claim term is to be read as a POSA would understand the claim term "not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (*en banc*). The specification of the '844 patent is dominated by a description of the sole embodiment, and "[a]lthough the specification need not present every embodiment or permutation of the invention and the claims are not limited to the preferred embodiment of the invention, neither do the claims enlarge what is patented beyond what the inventor has described as the invention." *Netword, LLC v. Centraal Corp.*, 242 F.3d 1347, 1352 (Fed. Cir. 2001) (internal citation omitted). While not uniquely dispositive, "a claim construction that excludes the preferred embodiment is highly disfavored. *See Vitronics*, 90 F.3d at 1583 (holding that a claim construction that excludes the preferred embodiment is "rarely, if ever, correct and would require highly persuasive evidentiary support")." *Duncan Parking Techs., Inc. v. IPS Grp., Inc.*,

914 F.3d 1347, 1364 (Fed. Cir. 2019); *see also see also Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1581 (Fed. Cir. 1996) ("We share the district court's view that it is unlikely that an inventor would define the invention in a way that excluded the preferred embodiment, or that persons of skill in this field would read the specification in such a way.").

3. When construing claim terms, the court may look outside the intrinsic record to extrinsic evidence, but such extrinsic evidence "is less significant than the intrinsic record in determining the legally operative meaning of claim language" and is considered "in general as less reliable than the patent and its prosecution history in determining how to read claim terms." *Phillips*, 415 F.3d at 1317, 1318 (citations and internal quotations omitted). While the opinion of an expert may be useful, "conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court. Similarly, a court should discount any expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent." *Id*. at 1318 (internal quotations omitted).

4. When interpreting the meaning of the asserted claims of the '844 patent, the claims themselves offer guidance. Under Federal Circuit precedent, "when an applicant uses different terms in a claim it is permissible to infer that he intended his choice of different terms to reflect a differentiation in the meaning of those terms." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys.*, 381 F.3d 1111, 1119 (Fed. Cir. 2004); *see also* ECF No. 319 at 17. This canon of claim construction aligns with the maxim that "[a] claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so." *Vederi, LLC v. Google, Inc.*, 744 F.3d 1376, 1383 (Fed. Cir. 2014) (quoting *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005)); *see also* ECF No. 319.

5. When construing the proper meaning of dependent claims, "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Phillips*, 415 F.3d at 1315; *see also Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1376 (Fed. Cir. 2019) ("The fact that claim 5 'further' adds this step indicates that this step was neither a necessary element of claim 4 nor required in the step of 'maintaining a dictionary' in independent claim 1."); *see also Pfizer Inc. v. Ranbaxy Labs.*, 457 F.3d 1284, 1291-92 (Fed. Cir. 2006) (holding that Pre-AIA §112 paragraph 4 acts to render invalid dependent claims that do not narrow the scope of the independent claim from which they depend) (citing *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006)). Further, "when a patent claim does not contain a certain limitation and another claim does, that limitation cannot be read into the former claim in determining either validity or infringement." *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1122 (Fed. Cir. 1985); *see also* ECF No. 319 at 9.

6. While a patentee may choose to act as their own lexicographer, to do so the patentee "must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning. It is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must clearly express an intent to redefine the term." *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (internal quotations and citations omitted); *see also* ECF No. 319 at 14-15. During Claim Construction, the Court found that the patentee had not acted as their own lexicographer in any instance in the '844 patent—all disputed terms were given their plain and ordinary meaning. *See generally* ECF No. 319.

7. When construing claims, "courts may not redraft claims, whether to make them operable or to sustain their validity. Even a nonsensical result does not require the court to redraft the claims of [the patent]. Rather, whereas here, claims are susceptible to only one reasonable interpretation and that interpretation results in a nonsensical construction of the claim as a whole, the claim must be invalidated." *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004) (internal citation and quotations omitted).

8. When the claim language is unambiguous and subject to only one reasonable interpretation, even if that interpretation does not include the preferred or lone embodiment, then the claim should be interpreted to exclude that embodiment. *See Lucent Techs., Inc. v. Gateway, Inc.*, 525 F.3d 1200, 1215-16 (Fed. Cir. 2008) ("Indeed, we have limited application of the maxim that claims should be construed to preserve their validity to situations in which we conclude, after reviewing all the intrinsic evidence, that the claim language is ambiguous. *Phillips*, 415 F.3d at 1327. However, where we conclude that the claim language is unambiguous, we have construed the claims to exclude all disclosed embodiments."); *see also Chef Am*., 358 F.3d at 1373-74; *Elekta Instrument S.A. v. O.U.R. Sci. Int'l., Inc.*, 214 F.3d 1302, 1308-09 (Fed. Cir. 2000)).

III. INFRINGEMENT

9. Pursuant to 35 U.S.C. § 271(e)(2), Sanofi must prove by a preponderance of the evidence that the proposed product described in Mylan GmbH's NDA No. 210605 would infringe at least one of the asserted claims. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1565 (Fed. Cir. 1997).

10. "Determination of infringement, whether literal or under the doctrine of equivalents, is a question of fact. A patentee claiming infringement must present proof that the accused product meets each and every claim limitation." *Forest Labs., Inc. v. Abbott Labs.*, 239

F.3d 1305, 1310 (Fed. Cir. 2001) (internal citation omitted). "[T]he burden remains with the patentee to prove infringement, not on the defendant to disprove it." *Welker Bearing Co. v. PHD, Inc.*, 550 F.3d 1090, 1095 (Fed. Cir. 2008).

11. Determining infringement is a two-step process, first requiring proper construction of the claim and second comparing the properly-construed claim to the accused product. *See, e.g.*, *Glaxo Inc.*, 110 F.3d at 1565. In *Glaxo*, the Federal Circuit held that this analysis remains substantially unchanged when the patentee seeks relief under § 271(e)(2), with the difference being that the second step of the analysis is forward-looking as the accused product has not yet been brought to market. *Id*. at 1570 ("The relevant inquiry is whether the patentee has proven by a preponderance of the evidence that the alleged infringer will likely market an infringing product. What is likely to be sold, or, preferably, what will be sold, will ultimately determine whether infringement exists.").

12. Sanofi failed to establish by a preponderance of the evidence that all limitations of claim 21 are satisfied by the Proposed Product. Because "[i]t is axiomatic that dependent claims cannot be found infringed unless the claims from which they depend have been found to have been infringed," non-infringement of claim 21 establishes non-infringement for dependent claims 22, 25, and 30 as well. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989). Even assuming for the sake of argument that Sanofi proved that the limitations of claim 21 were satisfied, which it did not, Sanofi additionally failed to prove infringement of dependent claims 25 and 30. As a result, Sanofi failed to establish infringement of any claim by a preponderance of the evidence.

IV. INVALIDITY

13. A patent challenger may overcome the presumption of validity by clear and convincing evidence that the patent does not satisfy one or more of the requirements found in

Title 35 of the United States Code. *See Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95-97 (2011). After the patent challenger has made a *prima facie* showing that the patent is invalid, the patentee bears the burden of producing rebuttal evidence. *See Prometheus Labs., Inc. v. Roxane Labs., Inc.*, 805 F.3d 1092, 1101 (Fed. Cir. 2015).

A. Priority Date

14. While the U.S. patent system allows for filing continuing patent applications claiming priority back to an earlier application, the continuing application can only receive the benefit of the parent application's priority date "if that parent fully supports the claims. If not supported in the parent application, fundamental fairness requires that claims to new matter receive, at best, the filing date of the continuing application." *Agilent Techs., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1383 (Fed. Cir. 2009). The earlier-filed application must comply with the written description and enablement requirements of 35 U.S.C. § 112 with respect to the claims of the later-filed application. *See* 35 U.S.C. § 120; *see also Trading Techs. Int'l, Inc. v. eSpeed, Inc.,* 595 F.3d 1340, 1359 (Fed. Cir. 2010); *see also Encyclopedia Britannica, Inc. v. Alpine Elecs. of Am., Inc*., 609 F.3d 1345, 1347 (Fed. Cir. 2010) (holding continuing application claiming priority to earlier-filed application through chain of continuing applications can only claim the earliest filing date from which that and all continuing applications in the chain complied with all requirements of § 120, with ultimate effect that the earlier publication of the foreign filing of the parent application rendered the patent invalid under § 102(b)).

15. Regarding written description, the purported priority document (*i.e.*, the earlier-filed application to which a claim of priority is made) must demonstrate with reasonable clarity to one skilled in the art that at the time of the filing date sought, the inventor was in possession of the invention claimed in the later application. *See New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1295 (Fed. Cir. 2002). Regarding enablement, the purported priority

document must be sufficient to enable one of skill in the art to practice the claimed invention without undue experimentation. *See Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1253 (Fed. Cir. 2004). As a result, the '844 patent cannot rely on claims filed after the claimed priority date to support a claim for adequate written description and enablement.

16. Contrary to what Sanofi may argue, *Mentor Graphics Corp. v. EVE-USA, Inc.*, does not hold otherwise because the relevant patent in that case was not a continuation application claiming priority to another earlier-filed application, and therefore the court's inquiry into the "originally-filed claims" to assist in satisfying the written description requirement did not involve a priority claim. 851 F.3d 1275, 1297 (Fed. Cir. 2017). Claims do not automatically provide written description support for themselves merely by being present in an application. As stated in *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co*:

> Furthermore, while it is true that original claims are part of the original specification, *In re Gardner*, 480 F.2d 879, 879 (CCPA 1973), ***that truism fails to address the question whether original claim language necessarily discloses the subject matter that it claims.*** Ariad believes so, arguing that original claims identify whatever they state, *e.g.*, a perpetual motion machine, leaving only the question whether the applicant has enabled anyone to make and use such an invention … We disagree that this is always the case. Although many original claims will satisfy the written description requirement, certain claims may not. For example, a generic claim may define the boundaries of a vast genus of chemical compounds, and yet the question may still remain whether the specification, including original claim language, demonstrates that the applicant has invented species sufficient to support a claim to a genus.

598 F. 3d 1336, 1349 (Fed. Cir. 2010) (emphasis added). In the context of continuation patents claiming priority to an earlier application, the question remains whether "the inventor had possession, as of the filing date ***of the application relied on***, of the specific subject matter later claimed by him." *Chiron Corp.*, 363 F.3d at 1255 (emphasis added) (quoting *In re Wertheim*, 541 F.2d 257, 262 (CCPA 1976). As also held by the Court in *Chiron Corp.*, where the "validity challenges to the independent claims coincide[s] with the validity challenges to the dependent

claims" then "the sameness of the inquiries permit[s] the treatment of all claims at once." 363 F.3d at 1260.

17. The patentee bears the burden of establishing entitlement to the asserted priority date. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1381-82 (Fed. Cir. 2015).

18. Because the patent applications to which the '844 patent claims priority do not provide adequate written description and enablement for the '844 patent's claims, the '844 patent is only entitled to claim priority to application No. 10/790,225 (filed March 2, 2004) or GB application 0304822.0 (filed March 3, 2003) if those applications contain written description and enablement support for the full scope of the claims of the '844 patent filed in application No. 15/156,616 (filed May 17, 2016). *See generally* JTX-3. Otherwise, the priority date for the '844 patent can be no earlier than May 17, 2016, the filing date of the '844 patent.

B. Obviousness

19. A claim is invalid as obvious if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious to a POSA as of the priority date. 35 U.S.C. § 103. "Obviousness is based on underlying factual findings, including: (1) the level of ordinary skill in the art; (2) the scope and content of the prior art; (3) the differences between the claims and the prior art; and (4) secondary considerations of nonobviousness, such as commercial success, long-felt but unmet needs, failure of others, and unexpected results." *Prometheus Labs.,* 805 F.3d at 1097; *see also Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17-18 (1966); *KSR Int'l Co v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The Supreme Court in *KSR Int'l Co v. Teleflex Inc.* held that the four Graham factors control the § 103 obviousness inquiry, clarifying that "[w]hile the sequence of these questions might be reordered in any particular case, the factors continue to define the inquiry that controls. If a

court, or a patent examiner, conducts this analysis and concludes the claimed subject matter was obvious, the claim is invalid under § 103." *Id.* at 407.

20. Not unlike the analysis for infringement, the obviousness analysis begins with determining the proper meaning and scope of each claim in suit, after which the "court must compare the prior art to claims as one of ordinary skill of art at the time of the invention would have done." *National Steel Car,* 357 F.3d at 1334. And "[a]lthough operational characteristics of an apparatus may be apparent from the specification, we will not read such characteristics into the claims when they cannot be fairly connected to the structure recited in the claims." *In re Hiniker Co.*, 150 F.3d 1362, 1368 (Fed. Cir. 1998). In the analogous case of *In re Hiniker*, the Federal Circuit found that while the patentee argued that there were "operational advantages that are inherent in its claimed invention" with respect to an improved use of particular mechanical forces, that "[t]he claims [did] not quantify this force and do not otherwise recite structure that would so limit their coverage." *Id*. The Court ultimately found that "[w]hen given their broadest reasonable interpretation, the claims on appeal sweep in the prior art, and the prior art would have directed an artisan of ordinary skill to make the combination cited by the examiner . . . ." *Id*. at 1368-69. Further, "Hiniker's proffered facts, including its evidence of secondary considerations of nonobviousness, are not commensurate with the claim scope and are therefore unpersuasive. The invention disclosed in Hiniker's written description may be outstanding in its field, but the name of the game is the claim." *Id*. at 1369.

21. The "product of routine optimization that would have been obvious to one of skill in the art" is not patentable. *Senju Pharm. Co. v. Lupin Ltd.,* 780 F.3d 1337, 1353 (Fed. Cir. 2015); *accord Pfizer, Inc. v. Apotex, Inc.,* 480 F.3d 1348, 1371 (Fed. Cir. 2007); *see also Unwired Planet, LLC v. Google Inc.,* 841 F.3d 995, 1003 (Fed. Cir. 2016) ("For [a] technique's

use to be obvious, the skilled artisan need only be able to recognize, based on her background knowledge, its potential to improve the device and be able to apply the technique.").

1. Level Of Ordinary Skill In The Art

22. Obviousness is determined from the perspective of a hypothetical person of ordinary skill in the art ("POSA") as of the priority date (assumed here to be March 3, 2003). *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138 (Fed. Cir. 1985).

23. The POSA is assumed to be aware of the pertinent art. *See In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998) ("The legal construct also presumes that all prior art references in the field of the invention are available to this hypothetical skilled artisan.").

24. "Factors that may be considered in determining level of skill include: type of problems encountered in art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field. Not all such factors may be present in every case, and one or more of them may predominate." *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962-63 (Fed. Cir. 1986); *see also Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007).

2. The Scope And Content Of The Prior Art

25. An invention constitutes prior art barring the issuance of a patent when that invention "was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent"—assumed here to be the claimed priority date of March 3, 2003. 35 U.S.C. § 102(a) (Pre-AIA). An invention also constitutes prior art if "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States"—assumed here to be one year prior to March 2, 2004: March 2, 2003. 35 U.S.C. §102(b) (Pre-AIA).

26. "A reference is considered publicly accessible 'upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it.'" *See Jazz Pharms., Inc. v. Amneal Pharms., Inc.*, 895 F.3d 1347, 1355-56 (Fed. Cir. 2018) (quoting *In re Wyer*, 655 F.2d 221, 226 (CCPA 1981)).

27. The scope of relevant prior art "necessarily encompasses not only the field of the inventor's endeavor but also any analogous arts." *In re GPAC Inc.*, 57 F.3d 1573, 1577-78 (Fed. Cir. 1995); *see, e.g.*, *In re Klein*, 647 F.3d 1343, 1348 (Fed. Cir. 2011) ("A reference qualifies as prior art for an obviousness determination under § 103 only when it is analogous to the claimed invention.").

28. In determining whether prior art is analogous, there are two relevant criteria: "(1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved." *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1237 (Fed. Cir. 2010) (quotations and citation omitted).

3. The Differences Between The Claimed Invention And The Prior Art

29. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l*, 550 U.S. at 416. Further, "the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id*. at 418. The obviousness analysis allows for the use of "common sense," with the Supreme Court's guidance that often a POSA "will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id*. at 420.

30. When analyzing obviousness and combining references, the POSA applies not only ordinary skill, but also ordinary creativity. *Id*. at 421 ("A person of ordinary skill is also a person of ordinary creativity, not an automaton."); *see also id*. at 417 ("if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.").

31. When combining multiple different pieces of prior art, such as two different patents' teachings, the Court may ask whether the POSA at the time would have had a motivation to combine these references, which may be found explicitly or implicitly in the references, in design incentives, market forces, in "any need or problem known in the field of endeavor at the time of invention and addressed by the patent" or in the background knowledge, creativity, and common sense of the POSA. *See id.* at 420-21; *ZUP, LLC v. Nash Mfg., Inc.*, 896 F.3d 1365, 1371 (Fed. Cir. 2018), *cert. denied*, 139 S.Ct. 1211 (2019); *Ritchie v. Vast Res., Inc.*, 563 F.3d 1334, 1337 (Fed. Cir. 2009) ("Among the inventions that the law deems obvious are those modest, routine, everyday, incremental improvements of an existing product or process that confer commercial value (otherwise they would not be undertaken) but do not involve sufficient inventiveness to merit patent protection.").

32. Obviousness may be established based on a single prior art reference read in view of the knowledge and understanding of the POSA at the priority date. *See Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1330-32 (Fed. Cir. 2009). When one piece of prior art discloses all elements of the asserted claims, and another is used for reference but "not rel[ied] on . . . for the disclosure of a particular element or teaching" the finder of fact is not required to find any motivation to combine the references. *Realtime Data,* 912 F.3d at 1373.

33. Similarly, precedent is clear that anticipation is the ultimate form of obviousness. *See, e.g.*, *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983) ("Anticipation requires the presence in a single prior art disclosure of all elements of a claimed invention arranged as in the claim. A prior art disclosure that 'almost' meets that standard may render the claim invalid under § 103; it does not 'anticipate.' Though it is never necessary to so hold, a disclosure that anticipates under § 102 also renders the claim invalid under § 103, for 'anticipation is the epitome of obviousness.'") (citations omitted); *Realtime Data, LLC*, 912 F.3d at 1376.

34. Further, prior art references must be considered as a whole, without undue focus on the claimed invention in a prior art patent. *See EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985) ("A reference must be considered for everything it *teaches* by way of technology and is not limited to the particular *invention* it is describing and attempting to protect. On the issue of obviousness, the combined teachings of the prior art as a whole must be considered) (emphasis in original). It is therefore improper to consider only one embodiment in a prior art reference containing several embodiments. *See Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) ("[T]he fact that a specific embodiment is taught to be preferred is not controlling, since ***all disclosures*** of the prior art, including unpreferred embodiments, ***must be considered.***") (emphasis added) (quoting *In re Lamberti*, 545 F.2d 747, 750 (C.C.P.A. 1976)).

35. In addition to considering all embodiments in a reference, and the prior art as a whole, the POSA also considers implicit—not just explicit—disclosures in the prior art. *See IXI IP, LLC v. Samsung Elecs. Co.*, 903 F.3d 1257, 1262-65 (Fed. Cir. 2018) (affirming Patent Trial and Appeal Board's finding of obviousness based on expert testimony discussing how the POSA

would understand the prior art reference "as implicitly describing an implementation" where the relevant network feature was located on a computer laptop despite an embodiment describing the feature as located on a cell phone because the exemplary embodiment did not foreclose the teaching that the feature could be located elsewhere).

36. Precedent is clear that when, like here, "all of the limitations of the patent were present in the prior art references, and the invention was addressed to a 'known problem,' '*KSR* . . . compels the grant of summary judgment of obviousness.'" *Wyers*, 616 F.3d at 1240 (citing *Ball Aerosol & Specialty Container, Inc. v. Ltd. Brands, Inc.*, 555 F.3d 984, 993 (Fed. Cir. 2009) (holding the district court erred when applying the "flexible inquiry" the Supreme Court laid out in *KSR* "by failing to take account of 'the inferences and creative steps,' or even routine steps, that an inventor would employ . . .").

4. Secondary Considerations

37. Ultimately, the patent-challenger bears the burden of persuasion with respect to obviousness, but the patentee bears the burden of production with respect to secondary considerations of nonobviousness. *ZUP, LLC*, 896 F.3d at 1373-74. Objective indicia may be a helpful part of the obviousness inquiry, but only if they are not tainted by hindsight bias. *See, e.g.*, *KSR Int'l*, 550 U.S. at 421 ("A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.").

a. Secondary Considerations Require A Nexus To The Claims

38. Secondary considerations can only weigh towards nonobviousness if they have a nexus to the claims in question. *See, e.g.*, *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311-12 (Fed. Cir. 2006) ("Evidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention and the commercial success. . . . Thus, if the commercial success is due to an unclaimed feature of the device, the commercial

success is irrelevant. So too if the feature that creates the commercial success was known in the prior art, the success is not pertinent."); *see also In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Pat. Litig.*, 676 F.3d 1063, 1080 n.6 (Fed. Cir. 2012) ("[C]ourts must exercise care in assessing proffered evidence of objective considerations, giving such evidence weight only where the objective indicia are attributable to the inventive characteristics of the discovery as claimed in the patent.") (internal citations and quotations omitted).

39. Federal Circuit precedent has maintained a consistent voice in holding that "objective evidence of non-obviousness must be commensurate in scope with the claims which the evidence is offered to support." *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983) (internal quotations and citations omitted); *see also In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) ("For objective evidence of secondary considerations to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the *claimed invention*.") (emphasis in original) (citing *Wyers*, 616 F.3d at 1246 and *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1369 (Fed. Cir. 2011)). As a result, "[w]here the offered secondary consideration actually results from something other than what is ***both claimed and novel*** in the claim, there is no nexus to the merits of the claimed invention." *Kao*, 639 F.3d at 1068 (emphasis added).

40. Thus, while objective evidence relating to a commercial embodiment that is coextensive with the claims triggers a presumption of nexus, there is no nexus if the commercial embodiment and claims are not "co-extensive" or if "the patented invention is only a small component of the product tied to the objective evidence." *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332-33 (Fed. Cir. 2019).

41. As a result, if the claims are broad enough to include both beneficial and non-beneficial devices, there is no nexus. *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1325, 1336 (Fed. Cir. 2010) ("Because the claims are broad enough to cover devices that either do or do not solve the 'short fill' problem, Abbott's objective evidence of non-obviousness fails because it is not 'commensurate in scope with the claims which the evidence is offered to support.'") (citation omitted).

42. Sanofi has not established any secondary considerations with a nexus to the claims of the '844 patent. But even if Sanofi had, "secondary considerations of nonobviousness … simply cannot overcome a strong *prima facie* case of obviousness." *Wyers.*, 616 F.3d at 1246; *see also Leapfrog Enter., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007).

b. Evidence Of A "Long-Felt But Unmet Need" Must Be Specific

43. In order for evidence of a long-felt but unmet need to weight towards nonobviousness, the alleged need must derive from underlying facts or data, not merely an expert's assertions that an alleged need was present. *See Perfect Web Techs.,* 587 F. 3d at 1333 (holding patent owner's contention of long-felt need based on bare assertion of patent-owner's expert that the patent provided "improved efficiency" without citing data or underlying facts was legally insufficient to overcome summary judgment of obviousness). Rather, there must be an articulated problem. *Texas Instruments, Inc. v. United States Int'l Trade Comm'n*, 988 F. 2d 1165, 1178 (Fed. Cir. 1993) ("[L]ong-felt need is analyzed as of the date of ***an articulated identified problem*** and evidence of efforts to solve that problem.") (emphasis added).

44. Moreover, the alleged long-felt but unmet need must be satisfied by the claimed invention, not by an unclaimed device or configuration. *See Sjolund v. Musland*, 847 F.2d 1573, 1582 (Fed. Cir. 1988) (holding evidence of a long-felt need in the prior art that was satisfied by the patentee's device was insufficient to support a finding of nonobviousness because the

configuration of that device was not part of the *claimed* invention, stating "the advantages ascribed [to that configuration] are irrelevant in terms of the obviousness analysis.").

45. Even if a patent owner provides evidence of a long-felt but unmet need, that evidence can only weight towards nonobviousness if there are material differences between the claimed invention and the prior art. *See Geo M. Martin Co. v. Alliance Mach. Sys. Int'l LLC*, 618 F.3d 1294, 1304 (Fed. Cir. 2010) ("Where the differences between the prior art and the claimed invention are as minimal as they are here, however, it cannot be said that any long-felt need was unsolved.").

c. Commercial Success

46. Commercial success may be relevant when considering whether an invention was obvious "because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art." *Merck & Co.,* 395 F.3d at 1376. In other words, the relevance of alleged commercial success is that it supports an inference that others would have taken advantage of a market opportunity if a nonobvious way to do so existed.

47. That said, commercial success does not support nonobviousness when the success comes from something other than the claimed invention, including marketing or other factors that prevent others from using prior art methods to avail themselves of a market opportunity. *See Ritchie*, 563 F.3d at 1336 ("The commercial success of a product can have many causes unrelated to patentable inventiveness; for example, the commercial success of an 'invention' might be due not to the invention itself but to skillful marketing of the product embodying the invention."); *see also Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000) ("A nexus between commercial success and the claimed features is required.").

48. Blocking patents may also preclude an inference of nonobviousness based upon commercial success because others may have avoided the market opportunity due to the "risk of infringement liability and associated monetary or injunctive remedies." *Acorda Therapeutics, Inc. v. Roxanne Labs., Inc.*, 903 F.3d 1310, 1337 (Fed. Cir. 2018). As the Federal Circuit explained in *Acorda*, analysis of blocking patents can be "relevant to understanding why others had not made, developed, or marketed that 'blocked' invention and, hence, to evaluating objective indicia of the obviousness of the later patent." *Id.*; *see also Merck & Co.,* 395 F.3d at 1377 (holding that commercial success is not significantly probative of non-obviousness where others are barred from acting on the prior art).

49. For example, when one company holds additional patents that block others from acting on a market opportunity, evidence of commercial success (or a long-felt but unmet need) does not necessarily support an inference that the invention was nonobvious. *See Digitronics Corp. v. New York Racing Ass'n, Inc.*, 553 F.2d 740, 749 (2nd Cir. 1977) (holding any evidence of "long-felt need" or commercial success "very likely was simply a reflection of the fact that the dominant company had no incentive to make the change because its former system … was good enough to dominate the market, and no one else was willing to make the needed investment further to upgrade its operation, in view of that domination."); *see also Boston Sci. Scimed, Inc. v. Cordis Corp.*, 554 F.3d 982, 991 (Fed. Cir. 2009) (finding the failure of others in the marketplace to develop the patented medical device was due to "difficulty in finding a suitable drug," not an inability to conceive of the patented invention; holding as a matter of law the claim invalid as obvious).

d. Self-Serving Statements Are Not "Industry Praise" Supporting An Inference Of Nonobviousness

50. While praise by a competitor or neutral party may suggest nonobviousness, evidence that a patent owner pays for or issues press releases about its own alleged invention does not support nonobviousness. *See, e.g.*, *In re Cree, Inc.*, 818 F.3d 694, 702 (Fed. Cir. 2016) ("While praise in the industry for a patented invention, and specifically praise from a competitor tends to indicate that the invention was not obvious, self-serving statements from researchers about their own work do not have the same reliability.") (citations and internal quotations omitted); *see also Bosch Auto. Serv. Sols., LLC v. Matal*, 878 F.3d 1027, 1038 (Fed. Cir. 2017) ("Bosch submitted evidence that its 3834 and 3834EZ tools received two 'Top 20 Tool' awards from an industry magazine. As with Bosch's other objective indicia arguments, the Board found that Bosch did not tie these tools to the claims of the '796 patent. We agree. Just as with Bosch's evidence of commercial success, Bosch presented no evidence to establish that the tools receiving these awards fall within the claimed subject matter of the '796 patent.").

51. Alleged industry praise also fails to support nonobviousness when it arises from commercial success or a dominant position in the industry. *Geo M. Martin*, 618 F.3d at 1304-05 (finding evidence of secondary considerations insufficient when the industry praise and commercial success arose primarily from the patentee's dominant market position and single-source solution).

C. Lack Of Written Description And Enablement

52. The first paragraph of pre-AIA 35 U.S.C. § 112 contains a requirement for written description in addition to a separate requirement for enablement—although the two often rise and fall together. *See Ariad Pharms.,* 598 F.3d at 1351-52. The sixth paragraph of pre-AIA 35 U.S.C. § 112 states that "[a]n element in a claim for a combination may be expressed as a means

or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." Unlike a claim term that has its plain and ordinary meaning, if a claim term is found to be a means-plus-function limitation the Court may construe the claim to "encompass only the disclosed structure and its equivalents" rather than "to cover all possible means that perform the recited function." *Biodex Corp. v. Loredan Biomedical, Inc.*, 946 F.2d 850, 863 (Fed. Cir. 1991).

1. Written Description

53. To satisfy the written description requirement in § 112, first paragraph, "the patent specification must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed. An applicant complies with the written description requirement by describing the invention, with all its claimed limitations." *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998) (citation and quotations omitted). Moreover, "[i]t is a truism that a claim need not be limited to a preferred embodiment. However, in a given case, the scope of the right to exclude may be limited by a narrow disclosure." *Id.*

54. In particular, when the disclosure in a patent specification is narrow, the patentee's "original disclosure serves to limit the permissible breadth of his later-drafted claims." *Id*. As the Federal Circuit clarified in its 2010 *en banc* decision in *Ariad Pharms.*, "the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date. . . . [T]he test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Ariad Pharms.*, 598 F.3d at 1351 (citations omitted).

As a result, if the specification does not show that the inventors actually invented what is claimed, the claim is invalid for lack of written description. *See id.*

55. The written description requirement in § 112 is important because it helps ensure that patentees are not granted disproportionally broad claims that extend beyond their actual contributions. *Atl. Res. Mktg. Sys., Inc. v. Troy*, 659 F.3d 1345, 1354 (Fed. Cir. 2011) (citing *In re Katz Interactive Call Processing Pat. Litig.*, 639 F.3d 1303, 1319 (Fed. Cir. 2011)) ("The purpose of the written description requirement is to ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification.").

56. Although always important, written description compliance becomes of heightened importance when a patentee seeks to enforce claims that were added later in the prosecution history in response to innovation from others. As the Federal Circuit recently explained in *Quake v. Lo*, 928 F.3d 1365 (Fed. Cir. 2019), a case with facts analogous to those at issue in this case:

> "The essence of the written description requirement is that a patent applicant, as part of the bargain with the public, must describe his or her invention so that the public will know what it is and that he or she has truly made the claimed invention." *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1298 (Fed. Cir. 2014). The written description requirement is satisfied if the inventor "convey[s] with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and demonstrate[s] that by disclosure in the specification of the patent." *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1348 (Fed. Cir. 2011) (quoting *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008)). "[T]he purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not, and ***the requirement is particularly important when, as here, claims are added later during prosecution in response to development by others***." *Agilent Techs., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1383 (Fed. Cir. 2009). Here, the first time Quake tried to cover random MPS with this specification was ***after the publication of Lo's patent application*** directed to random MPS: Quake then canceled all his pending claims and replaced them with claims covering random MPS, ***creating a mismatch between the claims and the***

> ***originally filed specification***. An invention is usually expressly described in the specification; there is no reasonable argument for that being the case here.

Id. at 1373-74 (emphasis added).

57. Notably, because the written description requirement is concerned with whether the inventor claims that which she has not invented, the written description requirement is not satisfied when a party merely argues that the POSA would have understood the possibility of some variation of the disclosure. *See, e.g.*, *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1165 (Fed. Cir. 2019) ("Further, to the extent Idenix argues that, although not disclosed, a POSA would have known to include fluorine at 2'-down based on its similarities to other halogens, that is insufficient for written description. A description that merely renders the invention obvious does not satisfy the written description requirement.") (citation and quotations omitted). In *Idenix*, the Federal Circuit held a patent invalid for lack of written description. *Id.* The patent owner argued that, even though a species of a compound was not disclosed in the specification, the POSA would have known she could have included "fluorine at 2'-down based on its similarities to other halogens[.]" *Id.* The Court disagreed, stating that "'[A] description that merely renders the invention obvious does not satisfy' the written description requirement." *Id.* (citing *Ariad*, 598 F.3d at 1352).

58. Although a lower level of detail may be required if a field is deemed "predictable" to satisfy the written description requirement, a specification that fails to disclose an invention still fails to satisfy written description. *D Three Enters., LLC v. SunModo Corp.*, 890 F.3d 1042, 1050 (Fed. Cir. 2018) (holding patent claims for washerless assemblies of the device using attachments other than the type of bracket disclosed in the earlier-filed application lacked written description and therefore could not claim priority date of earlier-filed application when the earlier-filed application "never uses the term washerless, or describes any other types of

attachment brackets that could be used"). In *D Three*, the Court found that an application "in no way contemplates the use of other types of attachment brackets in a washerless assembly" and found the patent invalid for lack of written description. *Id.* at 1050, 1052. As the Federal Circuit has stated, a specification fails the written description requirement when, as here, "the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

2. Enablement

59. The enablement requirement in § 112 requires that the disclosure enable the POSA to make and use the full scope of the claimed invention. As the Federal Circuit made clear in *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361 (Fed. Cir. 1997), "[t]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'" and further, "[t]ossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." *Id.* at 1365-66 (citation omitted). *Genentech* further states that:

> It is true . . . that a specification need not disclose what is well known in the art. However, that general oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of ***minor*** details does not cause a specification to fail to meet the enablement requirement. However, when there is ***no disclosure*** of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.

Id. at 1366 (emphasis added) (internal citations omitted). Thus, when there is no disclosure on some aspect of a claimed invention, merely citing to knowledge of the POSA cannot substitute for disclosure that should have been in the specification.

60. "Enablement serves the dual function in the patent system of ensuring adequate disclosure of the claimed invention and of preventing claims broader than the disclosed invention. This important doctrine prevents both inadequate disclosure of an invention and overbroad claiming that might otherwise attempt to cover more than was actually invented." *MagSil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1380-81 (Fed. Cir. 2012) (citation omitted).

61. "Enabling the full scope of each claim is 'part of the quid pro quo of the patent bargain.' A patentee who chooses broad claim language must make sure the broad claims are fully enabled." *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008) (quoting *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003)).

V. REMEDIES

62. It is axiomatic that an invalid patent cannot be infringed. 35 U.S.C. § 282; *see, e.g.*, *IPXL Holdings, LLC v. Amazon.com, Inc*, 430 F.3d 1377, 1380 (Fed. Cir. 2005) ("Because the claims in suit are invalid, we need not visit the question of whether the district court erred in determining that the claims were not infringed.").

63. A patent owner is only entitled to a remedy under 35 U.S.C. § 271(e)(4) if a valid patent claim is infringed. Here, Sanofi has failed to prove infringement and is therefore not entitled to any remedies. Defendants, on the other hand, have shown by clear and convincing evidence that the asserted claims are invalid as obvious and for lack of written description and lack of enablement. Defendants are therefore entitled to a judgment of invalidity and noninfringement of claims 21, 22, 25, and 30 of the '844 patent.

64. Should the Court find the '844 patent is valid but only claim 22 is infringed, Sanofi is not entitled to an order under 35 U.S.C. § 271(e)(4)(A) that would delay the possible approval date of Mylan GmbH's NDA until after the expiration of the '844 patent. 35 U.S.C. §271(e)(4)(A). Only patents practiced by the patent owner may be listed in the Orange Book. *See, e.g.*, 21 CFR § 314.53(b) (addressing patent information that must and must not be submitted when filing an original NDA). If a claim is not practiced by the patent owner, such as claim 22 in this case, which Sanofi admits is not practiced by the Lantus SoloSTAR pen, the remedies for practiced patents should not attach, at least because such remedies would be inequitable. Further, orders directing the FDA not to approve a drug until an Orange Book patent expires are based on the premise that the FDA approved the initial brand-name drug composition and product information based on what was actually submitted and approved, and a generic seeking to market the same drug for the same use can therefore follow the same approval path. For these reasons, to the extent the Court determines only claim 22 is valid and infringed, then the Court should consider the "well-established principles of equity" to determine whether to grant or deny injunctive relief under "the traditional four-factor framework that governs the award of injunctive relief." *eBay Inc. v. MercExchange, LLC.*, 547 U.S. 388, 391, 394 (2006).

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